EPA Registration No. 3282-81 vol. 2

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL, SAFETY
AND POLLUTION PREVENTION

MAY 15 2014

David Swain
Reckitt Benckiser LLC
339 Interpace Parkway
Parsippany, NJ 07054

Subject: Amendment to add alternate formulations for the following products:

3282-65	**D-Con Mouse-Prufe II**
3282-66	**D-Con Pellets Generation II**
3282-74	**D-Con Bait Pellets II**
3282-81	**D-Con Ready Mixed Generation II**

Submission Date: February 6, 2014

Dear Mr. Swain:

The amendments referred to above, submitted under FIFRA, are **NOT** acceptable. A summary of the Agency's response is below:

These amendments would not change the overall formulation of the products or the way they are used. Only a single inert ingredient would be substituted at an equivalent percentage. EPA does not believe the measures contained in these proposed amendments are sufficient to address the concerns that gave rise to the NOIC. As EPA stated in the NOIC, the Agency "has determined that all consumer-use rodenticide bait products must be used in, and sold with, protective bait stations reasonably anticipated not to release the rodenticide bait, and has further determined that consumer-use rodenticides must not contain second generation anti-coagulants as active ingredients." The amended registrations you propose contain second generation anti-coagulants as active ingredients, and do not provide the products will be sold in protective bait stations reasonably anticipated not to release the rodenticide bait. These two aspects of the applications are sufficient to cause EPA to conclude that those amended registrations would not comply with the standard for registration set forth in section 3(c)(5) of FIFRA. Reckitt-Benckiser is, of course, free to argue in the cancellation hearing that these amended registrations meet the standard for registration in FIFRA (and thus should be allowed at the conclusion of the hearing). But until the cancellation process is concluded, EPA does not intend to consider amendments to the registrations involved in the cancellation action that, like the ones at issue here, do not comply with the determinations in the NOIC.

If you have any questions, please contact Gene Benbow at (703) 347-0235 or via email at benbow.gene@epa.gov.

Sincerely,

Meredith Laws
Branch Chief
Insecticide-Rodenticide Branch
Registration Division (7505P)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL, SAFETY
AND POLLUTION PREVENTION

FEB 2 4 2014

Hal Ambuter
Reckitt Benckiser Inc.
Morris Corporate Center IV, 399 Interpace Parkway
Parsippany, NJ 07054

Subject: Amendment to simplify label language in response to the NOIC
EPA Registration No./Primary Brand Name

3282-81 **D-Con Ready Mixed Generation II**

Submission Date: August 13, 2013

Dear Mr. Ambuter:

The amendment referred to above, submitted under FIFRA, is **NOT** acceptable. A summary of our response is below:

These amendments would purportedly make the labels "easy to read and understand" and would "further reduce the opportunities for accidental exposure to children, pets and non-target wildlife from these products, thus addressing the concerns EPA identified in the Agency's February 5, 2013 Notice of Intent to Cancel (NOIC), and rendering the NOIC unnecessary." As the Agency has previously made clear to Reckitt-Benckiser, EPA does not believe the measures contained in these proposed amendments are sufficient to address the concerns that gave rise to the NOIC. As EPA stated in the NOIC, the Agency "has determined that all consumer-use rodenticide bait products must be used in, and sold with, protective bait stations reasonably anticipated not to release the rodenticide bait; and has further determined that consumer-use rodenticides must not contain second generation anti-coagulants as active ingredients." Leaving aside certain other questions raised by the amendments, the amended registrations you propose contain second generation anti-coagulants as active ingredients, and do not provide the products will be sold in protective bait stations reasonably anticipated not to release the rodenticide bait. These two aspects of the applications are sufficient to cause EPA to conclude that those amended registrations would not comply with the standard for registration set forth in section 3(c)(5) of FIFRA. Reckitt-Benckiser is, of course, free to argue in the cancellation hearing that these amended registrations meet the standard for registration in FIFRA (and thus should be allowed at the conclusion of the hearing). But until the cancellation process is concluded, EPA does not intend to consider amendments to the registrations involved in the cancellation action that, like the ones at issue here, do not comply with the determinations in the NOIC.

If you have any questions, please contact Gene Benbow at (703) 347-0235 or via email at benbow.gene@epa.gov.

Sincerely,

Meredith Laws
Branch Chief
Insecticide-Rodenticide Branch
Registration Division (7505P)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL, SAFETY
AND POLLUTION PREVENTION

JUN 14 2013

Heather Bjornson
Reckitt Benckiser Inc.
Morris Corporate Center IV
399 Interspace Parkway
Parsippany, NJ 07054

Subject: Notification to add and additional container size
d-CON Ready Mixed Generation II
EPA Registration No. 3282-81
Your application dated May 15, 2013

Dear Ms. Bjornson:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10. The Agency has conducted a review and finds that the action requested does not fall within the scope of PRN 98-10. A summary of our findings include:

1. The proposed additional container size (8 lbs.) is inconsistent with PRN 98-10.
2. This type of notification is not acceptable for a product that is currently the subject of a Notice of Intent to Cancel.
3. Increasing the packaging size raises potential risk and cost issues with respect to existing stocks (for a product subject to an NOIC).

The Registration Division has therefore determined that this action is **denied** and no further processing of this action will occur. If you have any questions, you may contact me at (703) 308-6249 or at hebert.john@epa.gov.

Sincerely,

John Hebert
Product Manager 07
Insecticide-Rodenticide Branch
Registration Division (7505P)

Internal deliberative information--*Privileged attorney-client communication*

Hebert, John

From: Perlis, Robert
Sent: Tuesday, June 11, 2013 11:30 AM
To: Sherman, Kelly; Garrison, Scott; Hebert, John
Subject: RE: Notification for 3282-81

Kelly:

[redacted]

Bob Perlis
Pesticides and Toxic Substances Law Office
Office of General Counsel
US EPA
(202) 564-5636

From: Sherman, Kelly
Sent: Monday, June 10, 2013 12:37 PM
To: Garrison, Scott; Hebert, John
Cc: Perlis, Robert
Subject: RE: Notification for 3282-81

John: [redacted]

Bob/Scott: [redacted]

Kelly Sherman
Immediate Office of the Director
Office of Pesticide Programs
U.S. Environmental Protection Agency
(703) 305-8401

From: Sherman, Kelly
Sent: Friday, June 07, 2013 3:45 PM
To: Garrison, Scott; Hebert, John
Cc: Perlis, Robert
Subject: RE: Notification for 3282-81

[redacted]

Kelly Sherman
Immediate Office of the Director
Office of Pesticide Programs
U.S. Environmental Protection Agency
(703) 305-8401

From: Garrison, Scott
Sent: Wednesday, June 05, 2013 3:16 PM
To: Sherman, Kelly; Hebert, John
Cc: Perlis, Robert
Subject: RE: Notification for 3282-81

Confidential communication for internal deliberations only. Attorney-client privilege. Do not distribute outside EPA.

[redacted]

Scott Garrison
Pesticides and Toxic Substances Law Office (2333A)
Office of General Counsel
202-564-4047
garrison.scott@epa.gov

From: Sherman, Kelly
Sent: Wednesday, June 05, 2013 1:05 PM
To: Garrison, Scott; Hebert, John
Cc: Perlis, Robert
Subject: RE: Notification for 3282-81

[redacted]

Kelly Sherman
Immediate Office of the Director
Office of Pesticide Programs
U.S. Environmental Protection Agency
(703) 305-8401

From: Garrison, Scott
Sent: Wednesday, June 05, 2013 12:46 PM
To: Sherman, Kelly; Hebert, John
Cc: Perlis, Robert
Subject: RE: Notification for 3282-81

Confidential communication for internal deliberations only. Attorney-client privilege. Do not distribute outside EPA.

[redacted]

Scott Garrison
Pesticides and Toxic Substances Law Office (2333A)
Office of General Counsel
202-564-4047
garrison.scott@epa.gov

From: Sherman, Kelly
Sent: Wednesday, June 05, 2013 12:13 PM
To: Hebert, John; Garrison, Scott
Subject: RE: Notification for 3282-81

[redacted]

[redacted]

Kelly Sherman
Immediate Office of the Director
Office of Pesticide Programs
U.S. Environmental Protection Agency
(703) 305-8401

From: Hebert, John
Sent: Wednesday, June 05, 2013 11:36 AM
To: Garrison, Scott
Cc: Sherman, Kelly
Subject: Notification for 3282-81

Scott – [redacted]

Thanks,
John

12 OZ AND 3, 8 LBS – OUTER BOX/PAIL
FRONT LABEL

(GOOD HOUSEKEEPING SEAL)

House Mice (will) eat through (the)(place)(bait) pack

d-CON®
READY MIXED BAITBITS

KILLS MICE AND RATS

CAN KILL IN ONE FEEDING*

* Rats and mice may consume a lethal dose in one feeding with first dead mice appearing 4 or 5 days after feeding begins.

Keep out of reach of children.
CAUTION: May be harmful or fatal if swallowed.
Read additional precautionary statements on back panel.

ACTIVE INGREDIENT:
Brodifacoum 3-[3-(4'-bromo-{1,1'-biphenyl}-4-yl)-1,2,3,4-tetrahydro-1-naphthalenyl]-4-hydroxy-2H-1-benzopyran-2-one.....0.005%
OTHER INGREDIENTS: 99.995%
TOTAL 100.000%

4 READY TO USE BAIT FILLED TRAYS
4 BAIT TRAYS
NET CONTENTS 4/3.0 OZ. (85g)
NET WT: 12 OZ. (340g)

16 READY TO USE BAIT FILLED TRAYS
NET WT 3 LBS. (1360g)

Net Contents: 8 lbs.

NOT ACCEPTABLE
See 6/14/13 letter

SATISFACTION GUARANTEED OR YOUR MONEY BACK
Call 1-800-228-4722

Important: For directions for use and first aid instruction in Spanish, please call 1-866-648-1819

12 OZ AND 3, 8 LBS – OUTER BOX/PAIL
BACK/SIDE LABEL

d-CON READY MIXED GENERATION II

KILLS RATS AND MICE
Kills Warfarin-Resistant House Mice and Warfarin-Resistant Norway Rats

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

READ THIS LABEL: Read this entire label and follow all use directions and use precautions.

IMPORTANT: Do not expose children, pets, or other nontarget animals to rodenticides. To help prevent accidents:

1. Store product not in use in a location out of reach of children and pets.

2. Apply bait in locations out of reach of children, pets, domestic animals and non-target wildlife, or in tamper-resistant bait stations. These stations must be resistant to destruction by children under six years of age and must be used in a manner that prevents such children from reaching into bait compartments and obtaining bait. If bait can be shaken from stations when they are lifted, units must be secured or otherwise immobilized. Even stronger bait stations are needed in areas open to hoofed livestock, raccoons, bears, other potentially destructive animals, or in areas prone to vandalism.

3. Dispose of product container, and unused, spoiled, and unconsumed bait as specified on this label.

USE RESTRICTIONS: This product may only be used to control House Mice, Norway Rats, and Roof Rats in and around homes, industrial, commercial, agricultural and public buildings. d-CON Ready Mixed Generation II may also be used in transport vehicles (ships, trains, aircraft) and in and around related port or terminal buildings. Do not use in sewers. Do not place bait in areas where there is a possibility of contaminating food or surfaces that come in direct contact with food. Do not broadcast bait.

SELECTION OF TREATMENT AREAS: Determine areas where rats or mice will most likely find and consume the bait. Generally, these are along walls, by gnawed openings, in or beside burrows, in corners and concealed places, between floors and walls, or in locations where their signs have been seen. Remove as much alternative food as possible. Use tamper-resistant bait stations wherever necessary (see **"IMPORTANT:"**).

APPLICATION DIRECTIONS:
(FOR 12 OZ. BOX ONLY: The amount of bait contained in the trays in this box is unlikely to be sufficient to kill more than 3 to 12 rats. More than one box may be needed to control larger infestations.

To Control Norway and Roof Rats: Place 1 – 4 bait trays per placement. Space placements at intervals of 15 – 30 feet in infested areas. If trays are not fed for 5 consecutive days, relocate them to other places where rodent activity exists and where placements consistent with the requirements of this label can be made. Maintain an uninterrupted supply of fresh bait for at least 10 days.

To Control House Mice: Open tray and apply ¼ - ½ oz. (1-2 tablespoons) of bait at 8 to 12 foot intervals in infested areas. Larger placements (up to 2 ounces) may be used at points of extremely high mouse activity. Maintain a supply of fresh bait for at least 15 days.

Check bait locations every 2 days for signs of feeding. Replenish bait if more than 1/2 of the original amount has been removed by rodents. Replace contaminated or spoiled bait immediately if rodent activity is still evident. Collect and dispose of all dead animals and leftover bait properly.
To prevent reinfestation, limit sources of rodent food, water and harborage as much as possible. If reinfestation does occur, repeat treatment. Where continuous source of infestation is present, establish permanent bait stations and replenish as needed.

PRECAUTIONARY STATEMENTS:
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
CAUTION: May be harmful or fatal if swallowed. Keep away from humans, domestic animals, and pets. Wash hands after handling bait. IF BAIT IS EATEN BY HUMANS, CALL A PHYSICIAN AT ONCE. For 24 hour emergency assistance, call your local Poison Control Center. IF BAIT IS EATEN BY ANIMALS OR PETS: Call your local veterinarian.
NOTE TO PHYSICIAN AND VETERINARIAN: This product may reduce the clotting ability of blood and cause hemorrhaging. The anticoagulant action of this product may produce prolonged prothrombin times for 20 – 30 days after exposure. If poisoning occurs, intramuscular and oral administration of Vitamin K1 is are indicated, as in poisoning from overdose of dicumarol (bishydroxy coumarin). **FOR HUMAN CASES:** Vitamin K1 is antidotal as doses of 10 to 20 mg (not mg/kg). Repeated treatments may need to be given up to 30 days (based on monitoring of prothrombin times). In sever cases, blood transfusions may be necessary. **FOR ANIMAL CASES:** Contains Brodificoum, and anticoagulant with a half life in the dog or 1-4 days. For dogs that have ingested or that are suspected of having ingested Brodifacoum, and/or have obvious symptoms, such as bleeding or have lowered prothrombin times, give Vitamin K1 as follows: Vitamin K1 is antidotal at 5 mg/kg intramuscularly. Oral Vitamin K1 should be given for up to 30 days at 5 mg/kg (based on monitoring of prothrombin times). In sever cases blood transfusions may be necessary.

ENVIRONMENTAL HAZARDS: This product is toxic to fish, birds and wildlife. This product can pose a secondary hazard to birds of prey and mammals. Do not apply directly to water.

STORAGE AND DISPOSAL

Do not contaminate water, food, feed by storage or disposal.

STORAGE: Store only in original container, in a dry place inaccessible to children and pets.

DISPOSAL: If empty: Non-refillable container. Do not reuse or refill container. Place in trash or offer for recycling if available. **If partly filled:** Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

NOTICE TO BUYER AND USER: Seller warrants that this product conforms to the chemical description on the label and is reasonably fit fir the purpose stated on the label when used in accordance with directions under conditions of use. This warranty does not extend to the use of this product contrary to label instructions, or under abnormal use conditions, or under conditions not reasonable foreseeable to Seller, and Buyer and User assumes the risk of any such use.

SELLER DISCLAIMS ALL OTHER WARRANTIES EXPRESSED OR IMPLIED INCLUDING ANY WARRANTY OR FITNESS OR MERCHANTABILITY. SELLER SHALL NOT BE LIABLE FOR CONSEQUENTIAL, SPECIAL OR INDIRECT DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT AND SELLER'S SOLE LIABIITY AND BUYER'S AND USER'S EXCLUSIVE REMEDY SHALL BE LIMITED TO THE REFUND OF THE PURCHASE PRICE.

Questions? Comments? Call 1-800-228-4722
Distributed by: Reckitt Benckiser Inc. Parsippany, NJ 07054(-xxxx)

EPA Reg. No.: 3282-81
EPA Est. No.: 475-MS-1; 2393-WI-1

MADE IN THE USA

Important: For directions for use and first aid instruction in Spanish, please call 1-866-648-1819

SATISFACTION GUARANTEED OR YOUR MONEY BACK
Call 1-800-228-4722

MADE IN THE USA

3 OZ. BAIT TRAY
FRONT PANEL

d-CON®
READY MIXED BAITBITS

KILLS MICE AND RATS

READY-TO-USE BAIT TRAY

Kills Warfarin-Resistant House Mice and Warfarin-Resistant Norway Rats

CAN KILL IN ONE FEEDING*

* Rats and mice may consume a lethal dose in one feeding with first dead mice appearing 4 or 5 days after feeding begins.

Keep out of reach of children.
CAUTION: May be harmful or fatal if swallowed.
Read additional precautionary statements on back panel.

ACTIVE INGREDIENT:

Brodifacoum 3-[3-(4'-bromo-{1,1'-biphenyl}-4-yl)-1,2,3,4-tetrahydro-1-naphthalenyl]-4-hydroxy-2H-1-benzopyran-2-one	0.005%
OTHER INGREDIENTS:	99.995%
TOTAL	100.000%

NET WT: 3 OZ. (85g)

3 OZ. BAIT TRAY
BACK PANEL
Kills Warfarin-Resistant House Mice and Warfarin-Resistant Norway Rats

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.
Read the entire label on the outer package before using this product. It is illegal to sell these bait trays individually.

PRECAUTIONARY STATEMENTS:
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
KEEP OUT OF REACH OF CHILDREN
Place bait in areas not accessible to children, pets, domestic animals or wildlife or in tamper-resistance bait boxes.
CAUTION: May be harmful or fatal if swallowed. Keep away from humans, domestic animals, and pets. Wash hands after handling bait. IF BAIT IS EATEN BY HUMANS, CALL A PHYSICIAN AT ONCE. For 24 hour emergency assistance, call your local Poison Control Center. IF BAIT IS EATEN BY ANIMALS OR PETS: Call your local veterinarian.
NOTE TO PHYSICIAN AND VETERINARIAN: This product may reduce the clotting ability of blood and cause hemorrhaging. The anticoagulant action of this product may produce prolonged prothrombin times for 20 – 30 days after exposure. If poisoning occurs, intramuscular and oral administration of Vitamin K1 is are indicated, as in poisoning from overdose of dicumarol (bishydroxy coumarin). **FOR HUMAN CASES:** Vitamin K1 is antidotal as doses of 10 to 20 mg (not mg/kg). Repeated treatments may need to be given up to 30 days (based on monitoring of prothrombin times). In sever cases, blood transfusions may be necessary. **FOR ANIMAL CASES:** Contains Brodificoum, and anticoagulant with a half life in the dog or 1-4 days. For dogs that have ingested or that are suspected of having ingested Brodifacoum, and/or have obvious symptoms, such as bleeding or have lowered prothrombin times, give Vitamin K1 as follows: Vitamin K1 is antidotal at 5 mg/kg intramuscularly. Oral Vitamin K1 should be given for up to 30 days at 5 mg/kg (based on monitoring of prothrombin times). In sever cases blood transfusions may be necessary.

ENVIRONMENTAL HAZARDS: This product is toxic to fish, birds and wildlife. This product can pose a secondary hazard to birds of prey and mammals. Do not apply directly to water.

ACTIVE INGREDIENT:
Brodifacoum 3-[3-(4'-bromo-{1,1'-biphenyl}-4-yl)-1,2,3,4-tetrahydro-1-naphthalenyl]-4-hydroxy-2H-1-benzopyran-2-one.....0.005%
OTHER INGREDIENTS: 99.995%
TOTAL 100.000%

Questions? Comments? Call 1-800-228-4722
Distributed by: Reckitt Benckiser Inc. Parsippany, NJ 07054(-xxxx)

EPA Reg. No.: 3282-81
EPA Est. No.: 475-MS-1; 2393-WI-1

12 OZ AND 3, 8 LBS – OUTER BOX/PAIL
FRONT LABEL

(GOOD HOUSEKEEPING SEAL)

House Mice (will) eat through (the)(place)(bait) pack

d-CON®
READY MIXED BAITBITS

KILLS MICE AND RATS

CAN KILL IN ONE FEEDING*

* Rats and mice may consume a lethal dose in one feeding with first dead mice appearing 4 or 5 days after feeding begins.

Keep out of reach of children.
CAUTION: May be harmful or fatal if swallowed.
Read additional precautionary statements on back panel.

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Brodifacoum 3-[3-(4'-bromo-{1,1'-biphenyl}-4-yl)-1,2,3,4-tetrahydro-1-naphthalenyl]-4-hydroxy-2H-1-benzopyran-2-one.....0.005%
OTHER INGREDIENTS: 99.995%
TOTAL 100.000%

4 READY TO USE BAIT FILLED TRAYS
4 BAIT TRAYS
NET CONTENTS 4/3.0 OZ. (85g)
NET WT: 12 OZ. (340g)

16 READY TO USE BAIT FILLED TRAYS
NET WT 3 LBS. (1360g)

Net Contents: 8 lbs.

SATISFACTION GUARANTEED OR YOUR MONEY BACK
Call 1-800-228-4722

Important: For directions for use and first aid instruction in Spanish, please call 1-866-648-1819

12 OZ AND 3, 8 LBS – OUTER BOX/PAIL
BACK/SIDE LABEL

d-CON READY MIXED GENERATION II

KILLS RATS AND MICE
Kills Warfarin-Resistant House Mice and Warfarin-Resistant Norway Rats

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

READ THIS LABEL: Read this entire label and follow all use directions and use precautions.

IMPORTANT: Do not expose children, pets, or other nontarget animals to rodenticides. To help prevent accidents:

1. Store product not in use in a location out of reach of children and pets.

2. Apply bait in locations out of reach of children, pets, domestic animals and non-target wildlife, or in tamper-resistant bait stations. These stations must be resistant to destruction by children under six years of age and must be used in a manner that prevents such children from reaching into bait compartments and obtaining bait. If bait can be shaken from stations when they are lifted, units must be secured or otherwise immobilized. Even stronger bait stations are needed in areas open to hoofed livestock, raccoons, bears, other potentially destructive animals, or in areas prone to vandalism.

3. Dispose of product container, and unused, spoiled, and unconsumed bait as specified on this label.

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Check bait locations every 2 days for signs of feeding. Replenish bait if more than 1/2 of the original amount has been removed by rodents. Replace contaminated or spoiled bait immediately if rodent activity is still evident. Collect and dispose of all dead animals and leftover bait properly.
To prevent reinfestation, limit sources of rodent food, water and harborage as much as possible. If reinfestation does occur, repeat treatment. Where continuous source of infestation is present, establish permanent bait stations and replenish as needed.

PRECAUTIONARY STATEMENTS:
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
CAUTION: May be harmful or fatal if swallowed. Keep away from humans, domestic animals, and pets. Wash hands after handling bait. IF BAIT IS EATEN BY HUMANS, CALL A PHYSICIAN AT ONCE. For 24 hour emergency assistance, call your local Poison Control Center. IF BAIT IS EATEN BY ANIMALS OR PETS: Call your local veterinarian.
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ENVIRONMENTAL HAZARDS: This product is toxic to fish, birds and wildlife. This product can pose a secondary hazard to birds of prey and mammals. Do not apply directly to water.

STORAGE AND DISPOSAL

Do not contaminate water, food, feed by storage or disposal.

STORAGE: Store only in original container, in a dry place inaccessible to children and pets.

DISPOSAL: If empty: Non-refillable container. Do not reuse or refill container. Place in trash or offer for recycling if available. **If partly filled:** Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

NOTICE TO BUYER AND USER: Seller warrants that this product conforms to the chemical description on the label and is reasonably fit fir the purpose stated on the label when used in accordance with directions under conditions of use. This warranty does not extend to the use of this product contrary to label instructions, or under abnormal use conditions, or under conditions not reasonable foreseeable to Seller, and Buyer and User assumes the risk of any such use.

SELLER DISCLAIMS ALL OTHER WARRANTIES EXPRESSED OR IMPLIED INCLUDING ANY WARRANTY OR FITNESS OR MERCHANTABILITY. SELLER SHALL NOT BE LIABLE FOR CONSEQUENTIAL, SPECIAL OR INDIRECT DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT AND SELLER'S SOLE LIABIITY AND BUYER'S AND USER'S EXCLUSIVE REMEDY SHALL BE LIMITED TO THE REFUND OF THE PURCHASE PRICE.

Questions? Comments? Call 1-800-228-4722
Distributed by: Reckitt Benckiser Inc. Parsippany, NJ 07054(-xxxx)

EPA Reg. No.: 3282-81
EPA Est. No.: 475-MS-1; 2393-WI-1

MADE IN THE USA

Important: For directions for use and first aid instruction in Spanish, please call 1-866-648-1819

SATISFACTION GUARANTEED OR YOUR MONEY BACK
Call 1-800-228-4722

MADE IN THE USA

3 OZ. BAIT TRAY
FRONT PANEL

d-CON®
READY MIXED BAITBITS

KILLS MICE AND RATS

READY-TO-USE BAIT TRAY

Kills Warfarin-Resistant House Mice and Warfarin-Resistant Norway Rats

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Read additional precautionary statements on back panel.

ACTIVE INGREDIENT:
Brodifacoum 3-[3-(4'-bromo-{1,1'-biphenyl}-4-yl)-1,2,3,4-tetrahydro-1-naphthalenyl]-4-hydroxy-2H-1-benzopyran-2-one.....0.005%
OTHER INGREDIENTS: 99.995%
TOTAL 100.000%

NET WT: 3 OZ. (85g)

3 OZ. BAIT TRAY
BACK PANEL
Kills Warfarin-Resistant House Mice and Warfarin-Resistant Norway Rats

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.
Read the entire label on the outer package before using this product. It is illegal to sell these bait trays individually.

PRECAUTIONARY STATEMENTS:
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
KEEP OUT OF REACH OF CHILDREN
Place bait in areas not accessible to children, pets, domestic animals or wildlife or in tamper-resistance bait boxes.
CAUTION: May be harmful or fatal if swallowed. Keep away from humans, domestic animals, and pets. Wash hands after handling bait. IF BAIT IS EATEN BY HUMANS, CALL A PHYSICIAN AT ONCE. For 24 hour emergency assistance, call your local Poison Control Center. IF BAIT IS EATEN BY ANIMALS OR PETS: Call your local veterinarian.
NOTE TO PHYSICIAN AND VETERINARIAN: This product may reduce the clotting ability of blood and cause hemorrhaging. The anticoagulant action of this product may produce prolonged prothrombin times for 20 – 30 days after exposure. If poisoning occurs, intramuscular and oral administration of Vitamin K1 is are indicated, as in poisoning from overdose of dicumarol (bishydroxy coumarin). **FOR HUMAN CASES:** Vitamin K1 is antidotal as doses of 10 to 20 mg (not mg/kg). Repeated treatments may need to be given up to 30 days (based on monitoring of prothrombin times). In sever cases, blood transfusions may be necessary. **FOR ANIMAL CASES:** Contains Brodificoum, and anticoagulant with a half life in the dog or 1-4 days. For dogs that have ingested or that are suspected of having ingested Brodifacoum, and/or have obvious symptoms, such as bleeding or have lowered prothrombin times, give Vitamin K1 as follows: Vitamin K1 is antidotal at 5 mg/kg intramuscularly. Oral Vitamin K1 should be given for up to 30 days at 5 mg/kg (based on monitoring of prothrombin times). In sever cases blood transfusions may be necessary.

ENVIRONMENTAL HAZARDS: This product is toxic to fish, birds and wildlife. This product can pose a secondary hazard to birds of prey and mammals. Do not apply directly to water.

ACTIVE INGREDIENT:
Brodifacoum 3-[3-(4'-bromo-{1,1'-biphenyl}-4-yl)-1,2,3,4-tetrahydro-1-naphthalenyl]-4-hydroxy-2H-1-benzopyran-2-one.....0.005%
OTHER INGREDIENTS: 99.995%
TOTAL 100.000%

Questions? Comments? Call 1-800-228-4722
Distributed by: Reckitt Benckiser Inc. Parsippany, NJ 07054(-xxxx)

EPA Reg. No.: 3282-81
EPA Est. No.: 475-MS-1; 2393-WI-1

Reckitt Benckiser

May 15, 2013

John Hebert, PM 7
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, 4th Floor
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

RE: d-CON® Ready Mixed Baitbits

Notification to add an additional size

Dear Mr. Hebert:

With this letter, Reckitt Benckiser LLC, D/B/A Reckitt Benckiser (Reckitt), is submitting the enclosed notification to add an additional container size.

You will find the following included to support this notification:

1) Notification application form,
2) One redline version of the label, and
3) One clean version of the label.

If you have any questions, please contact me at (973) 404-2995 (direct dial) or email at Heather.Bjornson@rb.com.

Sincerely,

Heather R Bj

Heather R. Bjornson
Senior Regulatory Associate

Please read Instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 2-28-95

EPA

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☑ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
3282-81	John Hebert	☑ None ☐ Restricted
4. Company/Product (Name)	PM#	
d-CON® Ready Mixed Baitbits	PM-7	

5. Name and Address of Applicant *(Include ZIP Code)*

Reckitt Benckiser Inc.
399 Interpace Parkway
Parsippany, NJ 07054-0225

☐ *Check if this is a new address*

6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No._____

Product Name_____

Section II

☐ Amendment - Explain Below
☐ Resubmission in response to Agency Letter dated_____.
☑ Notification - Explain below.
☐ Final printed labels in response to Agency Letter dated _____.
☐ "Me Too" Application.
☐ Other - explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Notification of additional container size.
This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling of the Confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section III

1. **Material This Product Will Be Packaged In:**

Child-Resistant Packaging	Unit Packaging		Water Soluble Packaging		2. Type of Container
☐ Yes* ☑ No	☑ Yes ☐ No		☐ Yes ☑ No		☑ Metal ☑ Plastic ☐ Glass ☐ Paper ☐ Other (Specify) _____
	If "yes," Unit Package wgt.	No. per container	If "Yes," Package wgt.	No. per container	
	3.0 oz	4			

* ***Certification must be submitted.***

3. Location of Net Contents Information	4. Size(s) of Retail Container	5. Location of Label Directions
☑ Label ☐ Container	12 oz (4/3 oz) / 8 lbs.	☑ On Label ☐ On Labeling accompanying product

6. Manner in Which Label is Affixed to Product ☑ Lithograph ☐ Paper glued ☐ Stenciled ☐ Other (_____)

Section IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this applicaiton.)*

Name	Title	Telephone No. (Include Area Code)
Heather R. Bjornson	Senior Regulatory Associate	(973) 404-2995

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false for misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received **(Stamped)**

2. Signature	3. Title
Heather R Bj	Senior Regulatory Associate
4. Typed Name	5. Date
Heather R. Bjornson	May 15, 2013

EPA Form 8570-1 (rev. 8-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant copy

Material Sent for Data Extraction

Reg. # 3282-81

Description: Notification documents

☐ Material(s) Sent to Data Extraction Contractors:

- ☐ New Stamped Label Dated _____
- ☒ Notification Dated 2/7/12
- ☐ New CSF(s) Dated _____
- ☐ Other: _____

☐ Decision #: 460604

☐ Other Action/Comments: _____

_____

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Jennifer Shines

Phone: 305-5967 Division: RD

Date: 2/9/12

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

FEB 0 7 2012

Ms. Heather Bjornson
Technology Sciences Group
1150 18th St., NW, Suite 1000
Washington, DC 20036

Subject: Notification to add alternate suppliers of inert ingredients
d-CON® Ready Mix Baitbits
EPA Reg. No. 3282-81

Dear Ms. Bjornson:

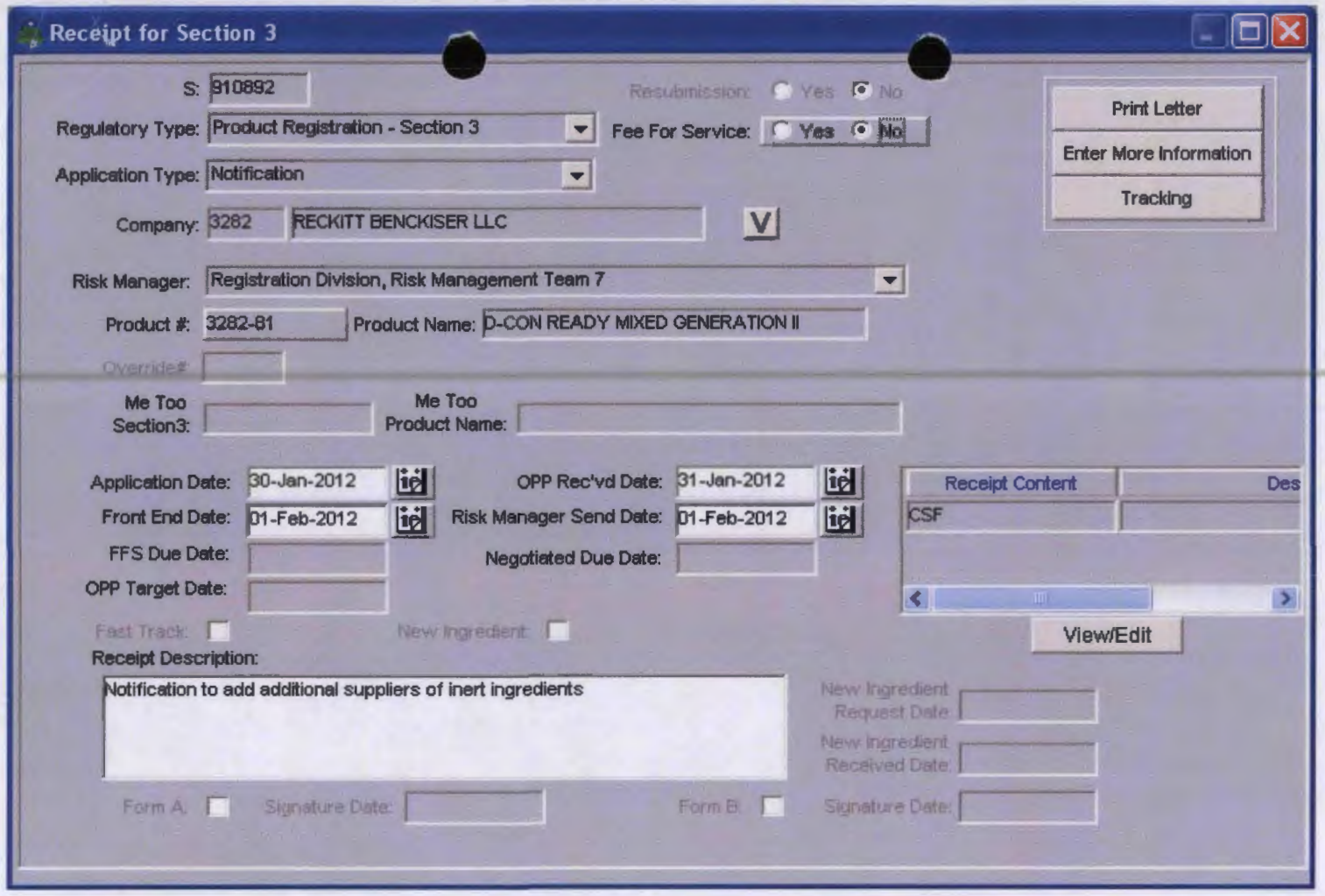
The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 dated January 30, 2012 for the product d-CON® Ready Mix Baitbits. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action(s) requested fall within the scope of PRN 98-10. The Confidential Statement of Formula (CSF) submitted with the application has been stamped "Notification" and will be placed in our records.

If you have any questions, please call me directly at 703-305-5967 or e-mail me at gaines.jennifer@epa.gov.

Sincerely,

Jennifer Gaines

Jennifer Gaines
Wildlife Biologist
Insecticide-Rodenticide Branch
Registration Division (7505P)
Office of Pesticide Programs


Receipt for Section 3
S: 910892
Resubmission: Yes No
Regulatory Type: Product Registration - Section 3
Fee For Service: Yes No
Application Type: Notification
Company: 3282 RECKITT BENCKISER LLC
Print Letter
Enter More Information
Tracking
Risk Manager: Registration Division, Risk Management Team 7
Product #: 3282-81
Product Name: D-CON READY MIXED GENERATION II
Override#:
Me Too Section3:
Me Too Product Name:
Application Date: 30-Jan-2012
OPP Rec'vd Date: 31-Jan-2012
Front End Date: 01-Feb-2012
Risk Manager Send Date: 01-Feb-2012
FFS Due Date:
Negotiated Due Date:
OPP Target Date:
Receipt Content
Des
CSF
Fast Track:
New Ingredient:
View/Edit
Receipt Description:
Notification to add additional suppliers of inert ingredients
New Ingredient Request Date:
New Ingredient Received Date:
Form A:
Signature Date:
Form B:
Signature Date:

Jew

Technology Sciences Group Inc.
1150 18th Street, NW, Suite 1000
Washington, D.C. 20036
Direct: (202) 828-8945
Fax: (202) 872-0745
E-Mail: hbjornson@tsgusa.com

Heather R. Bjornson
Senior Regulatory Consultant

January 30, 2012

John Hebert
Insecticide - Rodenticide Branch
Office of Pesticide Products
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

RE: ***d-Con® Ready Mix Baitbits*** **(EPA Reg. No. 3282-81)**

Notification to add additional suppliers of inert ingredients

Dear Mr. Hebert:

Technology Sciences Group, on behalf of Reckitt Benckiser, is submitting the enclosed notification to add additional suppliers for two inert ingredients to the alternate formulation Confidential Statement of Formula. Please do not hesitate to contact me with any questions.

Sincerely,

Heather R. Bjornson

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060. Approval expires 2-28-95

EPA

United States
Environmental Protection Agency
Washington, DC 20460

- [ ] Registration
- [ ] Amendment
- [x] Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
3282-81	John Hebert	[x] None [ ] Restricted
4. Company/Product (Name) d-CON Ready Mix Baitbits	**PM#** 4B	

5. Name and Address of Applicant *(Include ZIP Code)*

Reckitt Benckiser Inc.
Morris Corporate Center IV, 399 Interpace Parkway
Parsippany, NJ 07054

[ ] *Check if this is a new address*

6. Expedited Reveiw. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

NOTIFICATION
NOTIFICATION
FEB 07 2012

EPA Reg. No. _____

Product Name _____

Section - II

- [ ] Amendment - Explain below.
- [ ] Resubmission in response to Agency letter dated _____
- [x] Notification - Explain below.
- [ ] Final printed labels in repsonse to Agency letter dated _____
- [ ] "Me Too" Application.
- [ ] Other - Explain below.

Explanation: **Use additional page(s) if necessary. (For section I and Section II.)**

This notification is to add additional suppliers to the alternate formulation CSF per PR Notice 98-10.

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling of the Confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packeging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes [ ] No	[ ] Yes [ ] No	[ ] Yes [ ] No	[ ] Metal [ ] Plastic [ ] Glass [ ] Paper [ ] Other (Specify)
* *Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
[ ] Label [ ] Container		[ ]

6. Manner in Which Label is Affixed to Product [ ] Lithograph [ ] Paper glued [ ] Stenciled [ ] Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Heather R. Bjornson,Technology Sciences Group, Inc.	Senior Regulatory Consultant	(202) 828-8945

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title
Heather R Bjornson	Regulatory Consultant to Reckitt Benckiser Inc.
4. Typed Name Heather R. Bjornson	**5. Date** January 30, 2012

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

NOTE TO FILE

The July 14, 2010 submission was a non-notification. The registrant submitted the documents so they could be added to the product file. A formal Agency letter was not sent to the registrant.

July 23, 2010

Reckitt Benckiser

July 14, 2010

Document Processing Desk (NON-NOTIF)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
One Potomac Yard, Room S-4900, 4th Floor
2777 S. Crystal Drive
Arlington, VA 22202

Attention: Mr. John Hebert, PM-7

Reference: Non-notification for additional packaging claim
Product Name: d-Con Ready Mixed Baitbits
EPA Registration Number: 3282-81
OPP ID Number: 298609

Dear Mr. Hebert:

This letter is to inform the agency that Reckitt Benckiser would like to add the following packaging claim to our master text label for the above referenced registration number:

(4 trays X 3 oz)

As per PR Notice 98-10 this action is considered a non-notification; however, we would like this information added to the file.

In support of this registration action, I have enclosed EPA form # 8570-1, OPP ID # 298609 that identifies this action.

If there is any other information that the agency needs to complete this submission, please feel free to contact me at 973-404-2717. Thank you for your assistance with this registration action.

Sincerely,

Christine Dellanno
Regulatory Affairs Associate

(Encl.)

Reckitt Benckiser Inc.
399 Interpace Parkway
P.O Box 225
Parsippany, NJ 07054
T (973) 404-2600
F (973) 404-5700

www.reckittbenckiser.com

Please read instructions on reverse before completing form. Form Approved, OMB No. 2070-0060, Approval expires 05-31-98

EPA

United States
Environmental Protection Agency
Washington, DC 20460

☐ **Registration**
☐ **Amendment**
☒ **Other**

OPP Identifier Number
298609

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
3282-81	John Hebert	☒ None ☐ Restricted
4. Company/Product (Name) d-Con Ready Mixed Baitbits	PM# # 7	

5. Name and Address of Applicant *(Include ZIP Code)*
Reckitt Benckiser Inc.
~~Morris Corporate Center IV~~
399 Interpace Parkway
Parsippany, NJ 07054-0225
☐ *Check if this is a new address*

6. **Expedited Review**. In accordance with FIFRA Section 3(c)(3)(b)(I), my product is similar or identical in composition and labeling to:
EPA Reg. No. _____
Product Name _____

Section – II

☐ Amendment - Explain below.
☐ Resubmission in response to Agency letter dated _____
☒ Notification - Explain below.
☐ Final printed labels in response to Agency letter dated _____
☐ "Me Too" Application
☐ Other - Explain below

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)

Non-Notification: to add the following packaging claim:

(4 trays X 3 oz)

This non-notification is consistent with the provisions of PR Notice 98-10 and EPA regulations 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this non-notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section – III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes* ☒ No	☒ Yes ☐ No	☐ Yes ☒ No	☐ Metal ☒ Plastic ☐ Glass ☐ Paper ☐ Other (Specifiy)
	If "Yes" Unit Packaging wgt. **3.0 oz** / No. per container **4**	If "Yes" Package wgt. / No. per container	

Certification must be submitted (on file)

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☒ Label ☐ Container	12 oz (4/3 oz)	☒ On Label ☐ On labeling accompanying product

6. Manner in Which Label is Affixed to Product ☒ Lithograph ☐ Paper glued ☐ Stenciled ☐ Other _____

Section – IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application)*

Name	Title	Telephone No. (Include Area Code)
Christine Dellanno	Regulatory Affairs Associate	973-404-2717

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received **(Stamped)**

2. Signature:	3. Title:	4. Typed Name:	5. Date:
	Regulatory Affairs Associate	Christine Dellanno	July 14, 2010

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete

White- EPA File Copy (original) Yellow- Applicant Copy

15 B 2-2

MATERIAL TO BE ADDED TO JACKET

REG # 3282-81

Description: PR Notice 2007-4 Changes

check all that apply		
☐	new stamped accepted label	Send to CSC
☐	new CSF	
☑	notification	

Instructions:

Attach this sheet to the top of **ALL** material sent to the file room (both loose paper and new material in jackets). This sheet will be imaged; a clear description will aid in finding material in the e-jacket. Remove staples from all material. If returning loose paper then hold together with a binder or paper clip. CSFs should be placed in the CSF folder (if returning jacket) or covered with a red CBI sheet (if returning loose paper). Material to be returned to file room should be place in the appropriate bin.

Reviewer's Name: Nicole Williams Date: _____

Phone: (703) 308-5551 Division: AD

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Liane Jenkins
Senior Registration Specialist
Reckitt Benckiser Inc.
399 Interpace Parkway
Parsippany, NJ 07054-0225

OCT 31 2008

Subject: Label Notification(s) for Pesticide Registration Notice 2007-4 and 98-10

Change inert ingredients to other ingredients
Added phone number for consumer questions

Dear Ms. Jenkins:

The Agency is in receipt of your Application(s) for Pesticide Notification(s) under Pesticide Registration Notice (PRN) 2007-4 and 98-10 dated September 25, 2008 for:

EPA Registration 3282-81 **d-CON Ready Mixed Baitbits**

The Registration Division (RD) has conducted a review of this request for applicability under PRN 2007-4 and 98-10 and finds that the label change(s) requested falls within the scope of PRN-2007-4 and 98-10. The label has been date-stamped "Notification" and will be placed in our records.

Please be reminded that 40 CFR Part 156.140(a)(4) requires that a batch code, lot number, or other code identifying the batch of the pesticide distributed and sold be placed on nonrefillable containers. The code may appear either on the label (and can be added by non-notification/PR Notice 98-10) or durably marked on the container itself.

If you have any questions, please contact me directly at 703-305-6249 or Nicole Williams of my staff at 703-308-8893.

Sincerely,

Linda Arrington
Notifications & Minor Formulations Team Leader
Registration Division (7505P)
Office of Pesticide Programs

Please read Instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 2-28-95

EPA

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☑ Other

OPP Identifier Number: 303691

Application for Pesticide - Section I

1. Company/Product Number: 3282-81
2. EPA Product Manager: John Hebert
3. Proposed Classification: ☑ None ☐ Restricted
4. Company/Product (Name): *d-CON® Ready Mixed Baitbits*
   PM#: PM-7
5. Name and Address of Applicant *(Include ZIP Code)*:
   Reckitt Benckiser Inc.
   399 Interpace Parkway
   Parsippany, NJ 07054-0225
   ☐ *Check if this is a new address*
6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to

NOTIFICATION
OCT 31 2008

EPA Reg. No. _____
Product Name _____

Section II

☐ Amendment - Explain Below
☐ Resubmission in response to Agency Letter dated _____.
☑ Notification - Explain below.
☐ Final printed labels in response to Agency Letter dated _____.
☐ "Me Too" Application.
☐ Other - explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Notification of label change per PR Notice 2007-4 to address the new Container Rule, PR Notice 97-6 for term "Inert" ingredients and phone number addition

Section III

1. **Material This Product Will Be Packaged In:**

Child-Resistant Packaging	Unit Packaging		Water Soluble Packaging		2. Type of Container
☐ Yes* ☑ No	☑ Yes ☐ No		☐ Yes ☑ No		☑ Metal ☑ Plastic ☐ Glass ☐ Paper ☐ Other (Specify) _____
* ***Certification must be submitted.***	If "yes," Unit Package wgt.	No. per container	If "Yes," Package wgt.	No. per container	
	3.0 oz	4			

3. Location of Net Contents Information: ☑ Label ☐ Container
4. Size(s) of Retail Container: 12 oz (4/3 oz)
5. Location of Label Directions: ☑ On Label ☐ On Labeling accompanying product
6. Manner in Which Label is Affixed to Product: ☑ Lithograph ☐ Paper glued ☐ Stenciled ☐ Other (_____)

Section IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this applicaiton.)*

Name	Title	Telephone No. (Include Area Code)
Liane Jenkins	Senior Registration Specialist	(973) 404-2781

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false for misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature: Liane Jenkins
3. Title: Senior Registration Specialist
4. Typed Name: Liane Jenkins
5. Date: September 25, 2008

RECKITT BENCKISER

September 25, 2008

~~Document Processing Desk (NOTIF)~~
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
One Potomac Yard, Room S4900
2777 S. Crystal Drive
Arlington, VA 22202

Attention: Linda Arrington

Ref.: **d-CON® Ready Mixed Baitbits**
- EPA Reg. No.: 3282-81
- OPP ID No.: 303691
- Label Change to meet PR Notice 97-6 and 2007-1

Dear Ms. Arrington,

Reckitt Benckiser is notifying the Agency of a few label changes made to the above mentioned registration. These changes should be allowed via Notification. All changes to the proposed Master label are indicted in red text. Below is a summary of these changes:

- Revising the Disposal Instruction as per PR Notice 2007-1. The revised language is taken directly from this PR Notice.
- Changing "Inert" Ingredients to "Other" ingredients as allowed by PR Notice 97-6
- Adding a phone number for consumers to call for questions.

The enclosed documents support this registration action:

- EPA Application of Pesticide Registration, Form 8570-1, OPP ID No. 303691
- Certification Statement as per PR Notice 95-2
- One copy of proposed label with changes highlighted in red text

Thank you for your assistance with this registration action. If you have any questions, please contact me at (973) 404-2781 or via e-mail at liane.jenkins@reckittbenckiser.com .

Sincerely,

Liane Jenkins

Liane Jenkins
Senior Registration Specialist

RECKITT BENCKISER INC.
Morris Corporate Center IV, 399 Interpace Parkway, P.O. Box 225, Parsippany, NJ 07054-0225
Tel. (973)-404-2600 • Fax (973)-404-5700

12 OZ AND 3 LB. OUTER BOX
FRONT LABEL

(GOOD HOUSEKEEPING SEAL)

NOTIFICATION
OCT 3 1 2008

d-CON®
READY MIXED BAITBITS

KILLS MICE AND RATS

CAN KILL IN ONE FEEDING
*Rats and mice may consume a lethal dose in one feeding with first dead rodents appearing 4 or 5 days after feeding begins.

Keep out of reach of children.
CAUTION: May be harmful or fatal if swallowed.
Read additional precautionary statements on back panel.

ACTIVE INGREDIENT:
Brodifacoum 3-[3-(4'-bromo-{1,1'-biphenyl}-4-yl)-1,2,3,4-tetrahydro-1-naphthalenyl]-4-hydroxy-2H-1-benzopyran-2-one.....0.005%
OTHER INGREDIENTS: 99.995%
TOTAL 100.000%

4 READY TO USE BAIT FILLED TRAYS
4 BAIT TRAYS
NET CONTENTS 4/3.0 OZ. (85g)
NET WT. 12 OZ. (340g)

16 READY TO USE BAIT FILLED TRAYS
NET WT. 3 LBS. (1360g)

Important: For Direction for use and first aid instruction in Spanish, please call 1-866-648-1019

12 OZ BOX AND 3 LB. OUTER BOX
BACK LABEL

d-CON READY MIXED GENERATION II

KILLS RATS AND MICE
Kills Warfarin-Resistant House Mice and Warfarin-Resistant Norway Rats

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

READ THIS LABEL: Read this entire label and follow all use directions and use precautions.

IMPORTANT: Do not expose children, pets, or other non target animals to rodenticides. To help prevent accidents:

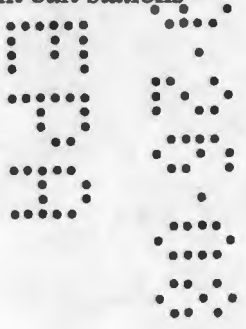
1. Store product not in use in a location out of reach of children and pets.

2. Apply bait in locations out of reach of children, pets, domestic animals and non-target wildlife, or in tamper-resistant bait stations. These stations must be resistant to destruction by children under six years of age and must be used in a manner that prevents such children from reaching into bait compartments and obtaining bait. If bait can be shaken from stations when they are lifted, units must be secured or otherwise immobilized. Even stronger bait stations are needed in areas open to hoofed livestock, raccoons, bears, other potentially destructive animals, or in areas prone to vandalism.

3. Dispose of product container, and unused, spoiled, and unconsumed bait as specified on this label.

USE RESTRICTIONS: This product may be used to control House Mice, Norway Rats, and Roof Rats in and around homes, industrial, commercial, agricultural and public buildings. d-CON Ready Mixed Generation II may also be used in transport vehicles (ships, trains, aircraft) and in and around related ports or terminal buildings. Do not use in sewers. Do not place bait in areas where there is a possibility of contaminating food or surfaces that come in direct contact with food. Do not broadcast bait.

SELECTION OF TREATMENT AREAS: Determine areas where rats or mice will most likely find and consume the bait. Generally, these are along walls, by gnawed openings, in or beside burrows, in corners and concealed places, between floors and walls, or in locations where rodents or signs of rodents have been seen. Remove as much alternative food as possible. Use tamper-resistant bait stations wherever necessary (see **"IMPORTANT:"**).



APPLICATION DIRECTIONS:
(FOR 12 OZ. BOX ONLY: The amount of bait contained in the trays in this box is unlikely to be sufficient to kill more than 3 to 12 rats. More than one box may be needed to control larger infestations.

To Control Norway and Roof Rats: Place 1 - 4 bait trays per placement. Space placements at intervals of 15 - 30 feet in infested areas. If trays are not fed for 5 consecutive days, relocate them to other places where rodent activity exists and where placements consistent with the requirements of this label can be made. Maintain an uninterrupted supply of fresh bait for at least 10 days.

To Control House Mice: Open tray and apply 1/4 - 1/2 oz. (1 - 2 level tablespoons) of bait at 8 to 12 foot intervals in infested areas. Larger placements (up to 2 ounces) may be needed at points of extremely high mouse activity. Maintain a supply of fresh bait for at least 15 days.

Check bait locations every 2 days for signs of feeding. Replenish bait if more than 1/2 of the original amount has been removed by rodents. Replace contaminated or spoiled bait immediately if rodent activity is still evident. Collect and dispose of all dead animals and leftover bait properly.
To prevent reinfestation, limit sources of rodent food, water and harborage as much as possible. If reinfestation does occur, repeat treatment. Where a continuous source of infestation is present, establish permanent bait stations and replenish as needed.

PRECAUTIONARY STATEMENTS:
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
CAUTION: May be harmful or fatal if swallowed. Keep away from humans, domestic animals, and pets. Wash hands after handling bait. IF BAIT IS EATEN BY HUMAS, CALL A PHYSICIAN AT ONCE. For 24 hour emergency assistance, call your local Poison Control Center. IF BAIT IS EATEN BY ANIMALS OR PETS: Call your local veterinarian.
NOTE TO PHYSICIAN AND VETERINARIAN: This product may reduce the clotting ability of the blood and cause hemorrhaging. The anticoagulant action of this product may produce prolonged prothrombin times for 20 to 30 days after exposure. If poisoning occurs, intramuscular and oral administration of Vitamin K_1 are indicated, as in poisoning from overdose of dicumarol (bishydroxy coumarin). **FOR HUMAN CASES**: Vitamin K_1 is antidotal at doses of 10 to 20 mg (not mg/kg). Repeated treatments may need to be given for up to 30 days (based on monitoring of prothrombin times). In severe cases, blood transfusions may be necessary. **FOR ANIMAL CASES**: Contains Brodifacoum, an anticoagulant with a half-life in the dog of 1 – 4 days. For dogs that have ingested or that are suspected of having ingested Brodifacoum, and/or have obvious poisoning symptoms, such as bleeding or have lowered prothrombin times, give Vitamin K_1 as follows: Vitamin K_1 is antidotal at 5 mg/kg intramuscularly. Oral Vitamin K_1 should be given for up to 30 days at 5 mg/kg (based on monitoring of prothrombin times). In severe cases blood transfusions may be necessary.

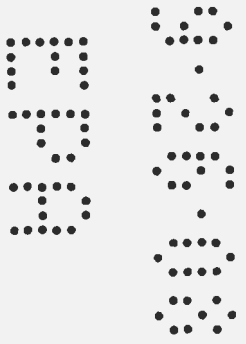
ENVIRONMENTAL HAZARDS: This product is toxic to fish, birds and wildlife. This product can pose a secondary hazard to birds of prey and mammals. Do not apply directly to water.

STORAGE AND DISPOSAL

STORAGE: Store only in original container, in a dry place inaccessible to children and pets.

DISPOSAL: If empty: Non-refillable container. Do not reuse or refill container. Place in trash or offer for recycling if available.
If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

Important: For Direction for use and first aid instruction in Spanish, please call 1-866-648-1819



12 OZ. BOX RIGHT SIDE PANEL

d-CON®
PELLETS GENERATION II

KILLS MICE AND RATS

Kills Warfarin-Resistant
House Mice and
Warfarin-Resistant
Norway Rats

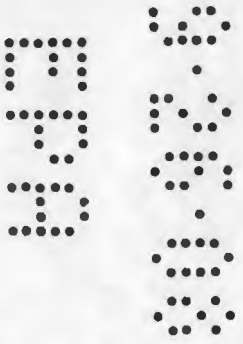
NOTICE TO BUYER AND USER: Seller warrants that this product conforms to the chemical description on the label and is reasonably fit for the purpose stated on the label when used in accordance with directions under normal conditions of use. This warranty does not extend to the use of this product contrary to label instructions, or under abnormal use conditions, or under conditions not reasonable foreseeable to Seller, and Buyer and User assumes the risk of any such use.

SELLER DISCLAIMS ALL OTHER WARRANTIES EXPRESSED OR IMPLIED INCLUDING ANY WARRANTY OR FITNESS OR MERCHANTABILITY. SELLER SHALL NOT BE LIABLE FOR CONSEQUENTIAL, SPECIAL OR INDIRECT DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT AND SELLER'S SOLE LIABILITY AND BUYER'S AND USER'S EXCLUSIVE REMEDY SHALL BE LIMITED TO THE REFUND OF THE PURCHASE PRICE.

EPA Reg. No. 3282-81
EPA Est. No. 475-MS-1; 2393-WI-1

SATISFACTION
GUARANTEED OR
YOUR MONEY BACK
Call 1-800-228-4722

Important: For Direction for use and first aid instruction in Spanish, please call 1-866-648-1819



12 OZ. BOX LEFT SIDE PANEL

d-CON®
PELLETS GENERATION II

KILLS RATS AND MICE

CAN KILL INONE FEEDING*

*Rats and mice may consume a lethal dose in one feeding with first dead rodents appearing 4 or 5 days after feeding begins.

MADE IN THE USA

d-CON BAITS:
KILLING RATS AND MICE IN AMERICA
FOR 50 YEARS

SATISFACTION
GUARENTEED OR
YOUR MONEY BACK
Call 1-800-228-4722

Questions? Comments? Call 1-800-228-4722
Distributed by:
Reckitt Benckiser Inc
Parsippany, NJ 07054

Important: For Direction for use and first aid instruction in Spanish, please call 1-866-648-1819

3 OZ. BAIT TRAY
FRONT PANEL

d-CON®
PELLETS GENERATION II

KILLS RATS AND MICE

READY-TO-USE BAIT TRAY

Kills Warfarin-Resistant House Mice and Warfarin-Resistant Norway Rats

CAN KILL INONE FEEDING*
*Rats and mice may consume a lethal dose in one feeding with first dead rodents appearing 4 or 5 days after feeding begins.

Keep out of reach of children.
CAUTION: May be harmful or fatal if swallowed.
Read additional precautionary statements on back panel.

ACTIVE INGREDIENT: Brodifacoum 3-[3-(4'-bromo-{1,1'-biphenyl}-4-yl)-1,2,3,4-tetrahydro-1-naphthalenyl]-4-hydroxy-2H-1-benzopyran-2-one.....0.005%
OTHER INGREDIENTS: 99.995%
TOTAL 100.000%

NET WT. 3 OZ. BAIT TRAY (85g)

3 OZ. BAIT TRAY
BACK PANEL

Kills Warfarin-Resistant Norway Rats and Warfarin-Resistant House Mice.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.
Read the entire label on the outer package before using this product. It is illegal to sell these bait trays individually.

PRECAUTIONARY STATEMENTS:
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
KEEP OUT OF REACH OF CHILDREN.
Place bait in areas not accessible to children, pets, domestic animals or wildlife or in tamper-resistance bait boxes.
CAUTION: May be harmful or fatal if swallowed. Keep away from humans, domestic animals, and pets. Wash hands after handling bait. IF BAIT IS EATEN BY HUMANS, CALL A PHYSICIAN AT ONCE. For 24 hour emergency assistance, call your local Poison Control Center. IF BAIT IS EATEN BY ANIMALS ORPETS: Call your local veterinarian.
NOTE TO PHYSICIAN AND VETERINARIAN: This product may reduce the clotting ability of the blood and cause hemorrhaging. The anticoagulant action of this product may produce prolonged prothrombin times for 20 to 30 days after exposure. If poisoning occurs, intramuscular and oral administration of Vitamin K_1 are indicated, as in poisoning from overdose of dicumarol (bishydroxy coumarin). **FOR HUMAN CASES**: Vitamin K_1 is antidotal at doses of 10 to 20 mg (not mg/kg). Repeated treatments may need to be given for up to 30 days (based on monitoring of prothrombin times). In severe cases, blood transfusions may be necessary. **FOR ANIMAL CASES**: Contains Brodifacoum, an anticoagulant with a half-life in the dog of 1 – 4 days. For dogs that have ingested or that are suspected of having ingested Brodifacoum, and/or have obvious poisoning symptoms, such as bleeding or have lowered prothrombin times, give Vitamin K_1 as follows: Vitamin K_1 is antidotal at 5 mg/kg intramuscularly. Oral Vitamin K_1 should be given for up to 30 days at 5 mg/kg (based on monitoring of prothrombin times). In severe cases blood transfusions may be necessary.

ENVIRONMENTAL HAZARDS: This product is toxic to fish, birds and wildlife. This product can pose a secondary hazard to birds of prey and mammals. Do not apply directly to water.

ACTIVE INGREDIENT: Brodifacoum 3-[3-(4'-bromo-{1,1'-biphenyl}-4-yl)-1,2,3,4-tetrahydro-1-naphthalenyl]-4-hydroxy-2H-1-benzopyran-2-one.....0.005%
OTHER INGREDIENTS: 99.995%
TOTAL 100.000%

Questions? Comments?
Call 1-800-228-4722
Distributed by:
Reckitt Benckiser Inc
Parsippany, NJ 07054

EPA Reg. No. 3282-81
EPA Est. No. 475-MS-1; 2392-WI-1

RECKITT BENCKISER

September 25, 2008

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
One Potomac Yard, Room S4900
2777 S. Crystal Drive
Arlington, VA 22202-4501

RE: d-CON Ready Mixed Baitbits
EPA Registration No.: 3282-81
Certification Statement per PR Notice 98-10

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Liane Jenkins

Liane Jenkins
Senior Regulatory Specialist

RECKITT BENCKISER INC.
Morris Corporate Center IV, 399 Interpace Parkway, P.O. Box 225, Parsippany, NJ 07054-0225
Tel. (973)-404-2600 • Fax (973)-404-5700

"Ambuter, Hal"
<Hal.Ambuter@reckittbenckiser.com>
10/29/2008 04:43 PM

To Nicole Williams/DC/USEPA/US@EPA
cc
bcc
Subject RE: Your EPA Notifications

History: This message has been replied to.

Nicole,

Pertaining to the recent notifications submitted on EPA registration numbers:

3282-88
3282-65
3282-66
3282-81
3282-74
3282-87
3282-86
3282-85

Notification of label changes per PR Notice 2007-4. These notifications are consistent with the guidance in PR Notice 2007-4 and the requirements of EPA's regulations at 40 CFR §§ 156.10, 156.140, 156.144, 156.146, and 156.156. No other changes have been made to the labeling or the Confidential Statement of Formula for these products. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if the amended labels are not consistent with the requirements of 40 CFR §§ 156.10, 156.140, 156.144, 156.146, and 156.156, these products may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Sincerely,

Hal Ambuter
Senior Regulatory Manager
Reckitt Benckiser
399 Interpace Parkway
Parsippany, NJ U.S.A. 07054-0225
· phone: 1-973-404-2716
· fax: 1-973-404-5702
· e-mail: hal.ambuter@reckittbenckiser.com

-----Original Message-----
From: Williams.Nicole@epamail.epa.gov [mailto:Williams.Nicole@epamail.epa.gov]
Sent: Wednesday, October 29, 2008 11:37 AM
To: Jenkins, Liane
Cc: Ambuter, Hal
Subject: Your EPA Notifications

The Agency is in receipt of your notifications and need to following documents submitted for us to perform a review of your products:

1. Please submit the certification statement for container and disposal language per PR Notice 2007-4. It is located on page 6 of the PR Notice.

Please submit this via email. You have 3 business days to respond.

Product# -

RECKITT BENCKISER

September 3, 2008

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Attention: John Hebert, PM-7

Ref.: **d-CON® Ready Mixed Baitbits**
- EPA Reg. No.: 3282-81
- OPP ID No.: 303686
- Final Printed Labels

Dear John,

Reckitt Benckiser is submitting Final Printed labels for the above mentioned Registration. These labels do not replace our currently approved EPA stamped Master Label. However, they reflect the labels that will be out on market.

The enclosed documents support this registration action:

- EPA Application of Pesticide Registration, Form 8570-1, OPP ID No. 303686
- Two (2) Copies of Final Printed Label for the following:
  - Outer label for the 4 count bait tray (4/3.0 oz)
  - Inner label for the 3 oz bait tray – this is not sold individually

If you have any questions, please contact me at (973) 404-2781 or via e-mail at liane.jenkins@reckittbenckiser.com .

Sincerely,

Liane Jenkins

Liane Jenkins
Senior Registration Specialist

RECKITT BENCKISER INC.
Morris Corporate Center IV, 399 Interpace Parkway, P.O. Box 225, Parsippany, NJ 07054-0225
Tel. (973)-404-2600 • Fax (973)-404-5700

Please read Instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 2-28-95

EPA

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☑ Other

OPP Identifier Number: 303686

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
3282-81	John Hebert	☑ None ☐ Restricted
4. Company/Product (Name)	PM#	
d-CON® Ready Mixed Baitbits	PM-7	

5. Name and Address of Applicant *(Include ZIP Code)*

Reckitt Benckiser Inc.
399 Interpace Parkway
Parsippany, NJ 07054-0225

☐ *Check if this is a new address*

6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No._____

Product Name_____

Section II

☐ Amendment - Explain Below
☐ Resubmission in response to Agency Letter dated_____.
☐ Notification - Explain below.

☑ Final printed labels in response to Agency Letter dated _____.
☐ "Me Too" Application.
☐ Other - explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcemnet action and penalties under sections 12 and 14 of FIFRA.
Submitted Final Print Label (2 copies)

Section III

1. **Material This Product Will Be Packaged In:**

Child-Resistant Packaging	Unit Packaging		Water Soluble Packaging		2. Type of Container
☐ Yes* ☑ No	☑ Yes ☐ No		☐ Yes ☑ No		☐ Metal ☐ Plastic ☐ Glass ☑ Paper ☐ Other (Specify) _____
	If "yes," Unit Package wgt.	No. per container	If "Yes," Package wgt.	No. per container	
	3.0 oz	4			

* ***Certification must be submitted.***

3. Location of Net Contents Information	4. Size(s) of Retail Container	5. Location of Label Directions
☐ Label ☑ Container	1.5 oz & 3 oz.	☑ On Label ☐ On Labeling accompanying product

6. Manner in Which Label is Affixed to Product: ☑ Lithograph ☐ Paper glued ☐ Stenciled ☐ Other (_____)

Section IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this applicaiton.)*

Name	Title	Telephone No. (Include Area Code)
Liane Jenkins	Senior Registration Specialist	(973) 404-2781

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false for misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title
Liane Jenkins	Senior Registration Specialist
4. Typed Name	**5. Date**
Liane Jenkins	September 3, 2008

EPA Form 8570-1 (rev. 8-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

d-CON Ready Mixed Baitbits

KILLS MICE & RATS
MATA RATONES Y RATAS

NOT REVIEWED
In Accordance with PR Notice 82-2
Based on Draft Labeling Dated
FEB. 13-1997

KILLS
WARFARIN-RESISTANT HOUSE MICE AND WARFARIN-RESISTANT NORWAY RATS

NOTICE TO BUYER AND USER:

Seller warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated on the label when used in accordance with directions under normal conditions of use. This warranty does not extend to the use of this product contrary to label instructions, or under abnormal use conditions, or under conditions not reasonably foreseeable to Seller, and Buyer and User assumes the risk of any such use.

SELLER DISCLAIMS ALL OTHER WARRANTIES EXPRESSED OR IMPLIED INCLUDING ANY WARRANTY OF FITNESS OR MERCHANTABILITY. SELLER SHALL NOT BE LIABLE FOR CONSEQUENTIAL, SPECIAL OR INDIRECT DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT AND SELLER'S SOLE LIABILITY AND BUYER'S AND USER'S EXCLUSIVE REMEDY SHALL BE LIMITED TO THE REFUND OF THE PURCHASE PRICE.

RATS AND MICE MAY CONSUME A LETHAL DOSE IN ONE FEEDING WITH FIRST DEAD RODENTS APPEARING 4 OR 5 DAYS AFTER FEEDING BEGINS.

Good Housekeeping Limited Warranty to Consumers ★ Promises Replacement or Refund if Defective

MADE IN THE USA

KEEP OUT OF REACH OF CHILDREN

CAUTION: May be harmful or fatal if swallowed. Read additional precautionary statements on back panel.

NET CONTENTS:
4/3.0 OZ. (85 g)
12 OZ. (340 g)

ACTIVE INGREDIENT:	
Brodifacoum 3-[3-(4'-bromo-[1,1'-biphenyl]-4-yl) -1,2,3,4-tetrahydro-1-naphthalenyl] -4-hydroxy-2H-1-benzopyran-2-one	0.005%
INERT INGREDIENTS	99.995%
TOTAL:	100.000%

www.d-conproducts.com

EPA Reg. No.: 3282-81
EPA Est. No.: 475-MS-1

4 Bait Trays **4 Bait Trays**

0127689

KILLS MICE & RATS
MATA RATONES Y RATAS

INSERT 90% UPC

0 19200 00202 8

IMPORTANTE:

Para instrucciones de uso y primeros auxilios en español por favor llame al 1-866-648-1819.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

READ THIS LABEL:

Read this entire label and follow all use directions and use precautions.

IMPORTANT:

Do not expose children, pets, or other nontarget animals to rodenticides.

To help prevent accidents:

1. Store product not in use in a location out of reach of children and pets.

2. Apply bait in locations out of reach of children, pets, domestic animals and non-target wildlife, or in tamper-resistant bait stations. These stations must be resistant to destruction by children under six years of age and must be used in a manner that prevents such children from reaching into bait compartments and obtaining bait. If bait can be shaken from stations when they are lifted, units must be secured or otherwise immobilized. Even stronger bait stations are needed in areas open to hoofed livestock, raccoons, bears, other potentially destructive animals, or in areas prone to vandalism.

3. Dispose of product container, and unused, spoiled, and unconsumed bait as specified on this label.

USE RESTRICTIONS:

This product may be used to control House Mice, Norway Rats, and Roof Rats in and around homes, industrial, commercial, agricultural and public buildings. d-CON® Ready Mixed Baitbits may also be used in transport vehicles (ships, trains, aircraft) and in and around related port or terminal buildings. Do not use in sewers. Do not place bait in areas where there is a possibility of contaminating food or surfaces that come in direct contact with food. Do not broadcast bait.

SELECTION OF TREATMENT AREAS:

Determine areas where rats or mice will most likely find and consume the bait. Generally, these are along walls, by gnawed openings, in or beside burrows, in corners and concealed places, between floors and walls, or in locations where rodents or signs of rodents have been seen. Remove as much alternative food as possible. Use tamper-resistant bait stations wherever necessary (see "IMPORTANT:").

APPLICATION DIRECTIONS:

The amount of bait contained in the trays in this box is unlikely to be sufficient to kill more than 3 to 12 rats. More than one box may be needed to control larger infestations.

TO CONTROL NORWAY AND ROOF RATS:

Place 1-4 bait trays per placement. Space placements at intervals of 15-30 feet in infested areas. If trays are not fed from for 5 consecutive days, relocate them to other places where rodent activity exists and where placements consistent with the requirements of this label can be made. Maintain an uninterrupted supply of fresh bait for at least 10 days.

TO CONTROL HOUSE MICE:

Open tray and apply 1/4 - 1/2 oz. (1-2 level tablespoons) of bait at 8 to 12 foot intervals in infested areas. Larger placements (up to 2 ounces) may be needed at points of extremely high mouse activity. Maintain a supply of fresh bait for at least 15 days.

Check bait locations every 2 days for signs of feeding. Replenish bait if more than 1/2 of the original amount has been removed by rodents. Replace contaminated or spoiled bait immediately if rodent activity is still evident. Collect and dispose of all dead animals and leftover bait properly.

To prevent reinfestation, limit sources of rodent food, water and harborage as much as possible. If reinfestation does occur, repeat treatment. Where a continuous source of infestation is present, establish permanent bait stations and replenish as needed.

PRECAUTIONARY STATEMENTS: HAZARDS TO HUMANS & DOMESTIC ANIMALS CAUTION:

May be harmful or fatal if swallowed. Keep away from humans, domestic animals, and pets. Wash hands after handling bait.

	FIRST AID
IF BAIT IS EATEN BY HUMANS	• CALL A PHYSICIAN AT ONCE. For 24 hour emergency assistance, call your local Poison Control Center.
IF BAIT IS EATEN BY ANIMALS OR PETS	• Call your local veterinarian.

NOTE TO PHYSICIAN AND VETERINARIAN

This product may reduce the clotting ability of the blood and cause hemorrhaging. The anticoagulant action of this product may produce prolonged prothrombin times for 20 to 30 days after exposure. If poisoning occurs, intramuscular and oral administration of Vitamin K_1 are indicated, as in poisoning from overdose of dicumarol (bishydroxy coumarin).
FOR HUMAN CASES: Vitamin K_1 is antidotal at doses of 10 to 20 mg (not mg/kg). Repeated treatments may need to be given for up to 30 days (based on monitoring of prothrombin times). In severe cases, blood transfusions may be necessary.
FOR ANIMAL CASES: Vitamin K_1 is antidotal at 5 mg/kg intramuscularly. Oral Vitamin K_1 should be given for up to 30 days at 5 mg/kg (based on monitoring of prothrombin times). In severe cases blood transfusions may be necessary.

ENVIRONMENTAL HAZARDS:

This product is toxic to fish, birds and wildlife. This product can pose a secondary hazard to birds of prey and mammals. Do not apply directly to water.

STORAGE AND DISPOSAL:

STORAGE: Store only in original container, in a dry place inaccessible to children and pets.
DISPOSAL: Do not reuse empty container. Securely wrap container and any unused bait in newspaper and discard in trash.

d-CON Ready Mixed Baitbits KILLS MICE & RATS
MATA RATONES Y RATAS

Rats and mice may consume a lethal dose in one feeding with first dead rodents appearing 4 or 5 days after feeding begins.

SATISFACTION GUARANTEED OR YOUR MONEY BACK

Questions? Comments?
Call 1-800-228-4722

Distributed by:
Reckitt Benckiser Inc.
Parsippany, NJ 07054-0224

4 Bait Trays

KEEP OUT OF REACH OF CHILDREN
CAUTION: SEE OUTER PACKAGE FOR DIRECTIONS AND ADDITONAL INFORMATION.

FIRST AID

IF BAIT IS EATEN BY HUMANS

- CALL A PHYSICIAN AT ONCE. For 24 hour emergency assistance, call your local Poison Control Center.

IF BAIT IS EATEN BY ANIMALS OR PETS

- Call your local veterinarian.

NOTE TO PHYSICIAN AND VETERINARIAN

This product may reduce the clotting ability of the blood and cause hemorrhaging. The anticoagulant action of this product may produce prolonged prothrombin times for 20 to 30 days after exposure. If poisoning occurs, intramuscular and oral administration of Vitamin K_1 are indicated, as in poisoning from overdose of dicumarol (bishydroxy coumarin). FOR HUMAN CASES: Vitamin K_1 is antidotal at doses of 10 to 20 mg (not mg/kg). Repeated treatments may need to be given for up to 30 days (based on monitoring of prothrombin times). In severe cases, blood transfusions may be necessary. FOR ANIMAL CASES: Vitamin K_1 is antidotal at 5 mg/kg intramuscularly. Oral Vitamin K_1 should be given for up to 30 days at 5 mg/kg (based on monitoring of prothrombin times). In severe cases blood transfusions may be necessary.

Questions? Comments? Call 1-800-228-4722
Distributed by Reckitt Benckiser Inc.,
Parsippany, NJ 07054-0224
Made in U.S.A © RBI 2008 0148617

EPA REG.No. 3282-81
EPA EST. No. 475-MS-1

H43

90-H0-6

TO OPEN LIFT AND PEEL BACK

d-CON

Ready Mixed Baithits

KILLS MICE & RATS

MATA RATONES Y RATAS

RATS AND MICE MAY CONSUME A LETHAL DOSE IN ONE FEEDING WITH FIRST DEAD RODENTS APPEARING 4 OR 5 DAYS AFTER FEEDING BEGINS.

KEEP OUT OF REACH OF CHILDREN
CAUTION: May be harmful or fatal if swallowed. Read additional precautionary statements on back panel.

NET WT.: 3 OZ.
Bait Tray (85 g)

KILLS
WARFARIN-RESISTANT HOUSE MICE AND WARFARIN-RESISTANT NORWAY RATS

ACTIVE INGREDIENT:
Brodifacoum 3-[3-(4'-bromo-[1,1'-biphenyl]-4-yl) -1,2,3,4-tetrahydro-1-naphthalenyl] -4-hydroxy-2H-1-benzopyran-2-one..... 0.005%
INERT INGREDIENTS 99.995%
TOTAL: 100.000%

1 Bait Tray

PRODUCT REREGISTRATION

SUPPORTING DOCUMENTATION

FOR

Case Name: Brodifacoum

Reg. No. 3282-81

This supporting documentation (in chronological order) includes:

- Old labels *(identified as "Superceded by label dated xx/xx/xx")*
- Unacceptable CSFs *(marked "Not Acceptable" and dated)*
- Product chemistry reviews
- Acute Toxicity reviews
- Efficacy reviews (if necessary)
- 90-day responses to PDCI (Form A and Form B)
- Administrative forms (Application for Reregistration, Certification to Data Citation, Data Matrix)
- Correspondence

Material to be added to a Mini-Jacket
(in the case where an e-Jacket exists)

Reg. No. 3282-81

Send to SIG: check box ☐

This material is:

- € New stamped-accepted label
- € New CSF
- € Notification
- € Final Printed Label
- € Other: _____

Instructions: Attach this notice on top of the material. It must be clipped all together and there should be NO STAPLES in the material. Then give the material with this coversheet to staff in the Information Services Center (Room 230).

Reviewer's Name: Steve

Phone: _____ **Division:** SRRD

Date: 12/3/08

stamped 10/10/06

12 OZ AND 3 LB. OUTER BOX

(GOOD HOUSEKEEPING SEAL)
(Graphic – Rodent)

d-CON®
READY MIXED BAITBITS

KILLS MICE AND RATS

Rats and mice may consume a lethal dose in one feeding with first dead rodents appearing 4 or 5 days after feeding begins.

KEEP OUT OF REACH OF CHILDREN.
CAUTION: May be harmful or fatal if swallowed.
Read additional precautionary statements on back panel.

ACTIVE INGREDIENT:
Brodifacoum 3-[3-(4'-bromo-{1,1'-biphenyl}-4-yl)-
1,2,3,4-tetrahydro-1-naphthalenyl]-4-hydroxy-2H-1-benzopyran-2-one. 0.005%
INERT INGREDIENTS: 99.995%
TOTAL 100.000%

NET WEIGHT 12 OZ. (340g)
NET CONTENTS 4/3.0 OZ. (85g)

NET WEIGHT 3 LBS. (1360g)
NET CONTENTS 16/3.0 oz (85g)

4 READY TO USE BAIT FILLED TRAYS
16 READY TO USE BAIT FILLED TRAYS

MADE IN THE USA

d-CON: Solving America's Rodent problems for over 50 years

SATISFACTION GUARANTEED OR YOUR MONEY BACK

12 OZ BOX AND 3 LB. OUTER BOX

KILLS RATS AND MICE
Kills Warfarin-Resistant House Mice and Warfarin-Resistant Norway Rats

(Graphics – Directions for Use)

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

READ THIS LABEL: Read this entire label and follow all use directions and use precautions. For information on this pesticide product (including health concerns, medical emergencies, or pesticide incidents), call the National Pesticide Telecommunications Network at 1-800-858-7378. Do not apply this product by any method not specified on this label.

IMPORTANT: Do not expose children, pets, or other non target animals to rodenticides. To help prevent accidents:

1. Store product not in use in a location out of reach of children and pets.

2. Apply bait in locations out of reach of children, pets, domestic animals and non-target wildlife, or in tamper-resistant bait stations. These stations must be resistant to destruction by children under six years of age and must be used in a manner that prevents such children from reaching into bait compartments and obtaining bait. If bait can be shaken from stations when they are lifted, units must be secured or otherwise immobilized. Even stronger bait stations are needed in areas open to hoofed livestock, raccoons, bears, other potentially destructive animals, or in areas prone to vandalism.

3. Dispose of product container, and unused, spoiled, and unconsumed bait as specified on this label.

USE RESTRICTIONS: This product may be used to control House Mice, Norway Rats, and Roof Rats indoors and against the outside walls of homes, industrial, commercial, agricultural and public buildings. d-CON Ready Mixed Baitbits may also be used in transport vehicles (ships, trains, aircraft) and in and against the outside walls of related port or terminal buildings. All outdoor placements must be made in tamper-resistant bait stations. Do not use this product in sewers. Do not contaminate human or pet food areas. Do not place near or inside ventilation duct openings. Do not broadcast bait.

12 OZ BOX AND 3 LB. OUTER BOX

SELECTION OF TREATMENT AREAS: Determine areas where rats or mice will most likely find and consume the bait. Generally, these are along walls, by gnawed openings, in or beside burrows, in corners and concealed places, between floors and walls, or in locations where rodents or signs of rodents have been seen. Remove as much alternative food as possible. Use tamper-resistant bait stations wherever necessary (see "IMPORTANT:").

APPLICATION DIRECTIONS:
The amount of bait contained in the trays in this box is unlikely to be sufficient to kill more than 3 to 12 rats. More than one box may be needed to control larger infestations.

To Control Norway and Roof Rats: Place 1 - 4 bait trays per placement. Space placements at intervals of 15 - 30 feet in infested areas. If trays are not fed for 5 consecutive days, relocate them to other places where rat activity exists and where placements consistent with the requirements of this label can be made. Maintain an uninterrupted supply of fresh bait for at least 10 days.

To Control House Mice: Open tray and apply 1/4 - 1/2 oz. (1 - 2 level tablespoons) of bait at 8 to 12 foot intervals in infested areas. Larger placements (up to 2 ounces) may be needed at points of extremely high mouse activity. Maintain a supply of fresh bait for at least 15 days.

Check bait locations every 2 days for signs of feeding. Replenish bait if more than 1/2 of the original amount has been removed by rodents. Replace contaminated or spoiled bait immediately if rodent activity is still evident. If trays are not fed from for 5 consecutive days, relocate them to other places where rodent activity exists and where placements consistent with the requirements of this label can be made. Collect and dispose of all dead animals and leftover bait properly.
Follow-Up (Rats and Mice): To prevent reinfestation, limit sources of rodent food, water and harborage as much as possible. If reinfestation does occur, repeat treatment. Where a continuous source of infestation is present, establish permanent bait stations and replenish as needed.

12 OZ BOX AND 3 LB. OUTER BOX

PRECAUTIONARY STATEMENTS:
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
CAUTION: May be harmful or fatal if swallowed. This material may reduce the clotting ability of the blood and cause bleeding. Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

FIRST AID Have label with you when obtaining treatment advice.	
If swallowed by human	• Call a Poison Control Center, doctor, or 1-800-228-4722 immediately for treatment advice. • Do not induce vomiting unless told to do so by the poison control center or doctor.
If swallowed by pet or animal	• Call a veterinarian immediately for treatment advice.
NOTE TO PHYSICIAN AND VETERINARIAN	
This product may reduce the clotting ability of the blood and cause hemorrhaging. The anticoagulant action of this product may produce prolonged prothrombin times for 20 to 30 days after exposure. If poisoning occurs, intramuscular and oral administration of Vitamin K_1 are indicated, as in poisoning from overdose of dicumarol (bishydroxy coumarin). **FOR HUMAN CASES**: Vitamin K_1 is antidotal at doses of 10 to 20 mg (not mg/kg). Repeated treatments may need to be given for up to 30 days (based on monitoring of prothrombin times). In severe cases, blood transfusions may be necessary. **FOR ANIMAL CASES**: Vitamin K_1 is antidotal at 5 mg/kg intramuscularly. Oral Vitamin K_1 should be given for up to 30 days at 5 mg/kg (based on monitoring of prothrombin times). In severe cases blood transfusions may be necessary.	

ENVIRONMENTAL HAZARDS: This product is toxic to fish, birds and wildlife. This product can pose a secondary hazard to birds of prey and mammals. Do not apply directly to water, or to areas where surface water is present or to inter-tidal areas below the mean high-water mark. Dogs and other predatory and scavenging mammals might be poisoned if they feed upon animals that have eaten this bait.

12 OZ BOX AND 3 LB. OUTER BOX

STORAGE AND DISPOSAL

STORAGE: Store only in original container, in a dry place inaccessible to children and pets.
DISPOSAL: If empty: Do not reuse empty container. Place in trash or offer for recycling if available.
If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

NOTICE TO BUYER AND USER: Buyer and User assume all responsibility for safety and risk associated with any use not in accordance with directions. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, SELLER SHALL NOT BE LIABLE FOR CONSEQUENTIAL, SPECIAL OR INDIRECT DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT AND SELLER'S SOLE LIABILITY AND BUYER'S AND USER'S EXCLUSIVE REMEDY SHALL BE LIMITED TO THE REFUND OF THE PURCHASE PRICE.

Distributed by: Reckitt Benckiser, Inc. Parsippany, NJ 07054
Questions? Comments? Call 1-800-228-4722

EPA Reg. No. 3282-81
EPA Est. No. 475-MS-1

MADE IN THE USA

SATISFACTION GUARANTEED OR YOUR MONEY BACK

d-CON BAITS: KILLING RATS AND MICE IN AMERICA FOR 50 YEARS

3 OZ. BAIT TRAY

(GOOD HOUSEKEEPING SEAL)

Ready To Use Bait Tray

d-CON®
READY MIXED BAITBITS

KILLS RATS AND MICE

Rats and House Mice may consume a lethal dose in one feeding with first dead rodents appearing 4 or 5 days after feeding begins.

Keep out of reach of children.
CAUTION: May be harmful or fatal if swallowed.
Read additional precautionary statements on back panel.

ACTIVE INGREDIENT:
Brodifacoum 3-[3-(4'-bromo-{1,1'-biphenyl}-4-yl)-
1,2,3,4-tetrahydro-1-naphthalenyl]-4-hydroxy-2H-1-benzopyran-2-one. 0.005%
INERT INGREDIENTS: 99.995%
TOTAL 100.000%

NET WEIGHT 3 OZ. BAIT TRAY (85g)

d-CON: Solving America's Rodent problems for over 50 years

SATISFACTION GUARANTEED OR YOUR MONEY BACK

3 OZ. BAIT TRAY

Kills Warfarin-Resistant Norway Rats and Warfarin-Resistant House Mice.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Read the entire label on the outer package before using this product. It is illegal to sell these bait trays individually.

PRECAUTIONARY STATEMENTS:

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: May be harmful or fatal if swallowed. This material may reduce the clotting ability of the blood and cause bleeding. Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Place bait in areas not accessible to children, pets, domestic animals or wildlife or in tamper-resistant bait boxes.

FIRST AID Have label with you when obtaining treatment advice.	
If swallowed by human	• Call a Poison Control Center, doctor, or 1-800-228-4722 immediately for treatment advice. • Do not induce vomiting unless told to do so by the poison control center or doctor.
If swallowed by pet or animal	• Call a veterinarian immediately for treatment advice.

NOTE TO PHYSICIAN AND VETERINARIAN

This product may reduce the clotting ability of the blood and cause hemorrhaging. The anticoagulant action of this product may produce prolonged prothrombin times for 20 to 30 days after exposure. If poisoning occurs, intramuscular and oral administration of Vitamin K_1 are indicated, as in poisoning from overdose of dicumarol (bishydroxy coumarin). **FOR HUMAN CASES**: Vitamin K_1 is antidotal at doses of 10 to 20 mg (not mg/kg). Repeated treatments may need to be given for up to 30 days (based on monitoring of prothrombin times). In severe cases, blood transfusions may be necessary. **FOR ANIMAL CASES**: Vitamin K_1 is antidotal at 5 mg/kg intramuscularly. Oral Vitamin K_1 should be given for up to 30 days at 5 mg/kg (based on monitoring of prothrombin times). In severe cases blood transfusions may be necessary.

3 OZ. BAIT TRAY

ENVIRONMENTAL HAZARDS: This product is toxic to fish, birds and wildlife. This product can pose a secondary hazard to birds of prey and mammals. Do not apply directly to water, or to areas where surface water is present or to inter-tidal areas below the mean high-water mark. Dogs and other predatory and scavenging mammals might be poisoned if they feed upon animals that have eaten this bait.

STORAGE AND DISPOSAL

STORAGE: Store only in original container, in a dry place inaccessible to children and pets.
DISPOSAL: If empty: Do not reuse empty container. Place in trash or offer for recycling if available.
If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

Distributed by: Reckitt Benckiser, Inc. Parsippany, NJ 07054
Questions? Comments? Call 1-800-228-4722

EPA Reg. No. 3282-81
EPA Est. No. 475-MS-1

MADE IN THE USA

SATISFACTION GUARANTEED OR YOUR MONEY BACK

d-CON BAITS: KILLING RATS AND MICE IN AMERICA FOR 50 YEARS

---

12 OZ AND 3 LB. OUTER BOX

(GOOD HOUSEKEEPING SEAL)
(Graphic - Rodent)

d-CON®
READY MIXED BAITBITS

KILLS MICE AND RATS

Rats and mice may consume a lethal dose in one feeding with first dead rodents appearing 4 or 5 days after feeding begins.

KEEP OUT OF REACH OF CHILDREN.
CAUTION: May be harmful or fatal if swallowed.
Read additional precautionary statements on back panel.

ACTIVE INGREDIENT:
Brodifacoum 3-[3-(4'-bromo-{1,1'-biphenyl}-4-yl)-1,2,3,4-tetrahydro-1-naphthalenyl]-4-hydroxy-2H-1-benzopyran-2-one.....0.005%
INERT INGREDIENTS: 99.995%

TOTAL 100.000%

NET WEIGHT 12 OZ. (340g)
NET CONTENTS 4/3.0 OZ. (85g)

NET WEIGHT 3 LBS. (1360g)
NET CONTENTS 16/3.0 oz (85g)

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4 READY TO USE BAIT FILLED TRAYS

16 READY TO USE BAIT FILLED TRAYS

MADE IN THE USA

d-CON: Solving America's Rodent problems for over 50 years

SATISFACTION GUARANTEED OR YOUR MONEY BACK

12 OZ BOX AND 3 LB. OUTER BOX

KILLS RATS AND MICE
~~Kills Warfarin-Resistant House Mice and Warfarin-Resistant Norway Rats~~

(Graphics - Directions for Use)

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

READ THIS LABEL: Read this entire label and follow all use directions and use precautions. For information on this pesticide product (including health concerns, medical emergencies, or pesticide incidents), call the National Pesticide Telecommunications Network at 1-800-858-7378. Do not apply this product by any method not specified on this label.

IMPORTANT: Do not expose children, pets, or other non target animals to rodenticides. To help prevent accidents:

1. Store product not in use in a location out of reach of children and pets.

2. Apply bait in locations out of reach of children, pets, domestic animals and non-target wildlife, or in tamper-resistant bait stations. These stations must be resistant to destruction by children under six years of age and must be used in a manner that prevents such children from reaching into bait compartments and obtaining bait. If bait can be shaken from stations when they are lifted, units must be secured or otherwise immobilized. Even stronger bait stations are needed in areas open to hoofed livestock, raccoons, bears, other potentially destructive animals, or in areas prone to vandalism.

3. Dispose of product container, and unused, spoiled, and unconsumed bait as specified on this label.

USE RESTRICTIONS: This product may be used to control House Mice, Norway Rats, and Roof Rats indoors and against the outside walls of homes, industrial, commercial, agricultural and public buildings. d-CON Ready Mixed Baitbits may also be used in transport vehicles (ships, trains, aircraft) and against the outside walls of related port or terminal buildings. Do not use in sewers. For use in non-food/non-feed areas. Do not contaminate human or pet food areas. Do not place near or inside ventilation duct openings. Do not broadcast bait.

12 OZ BOX AND 3 LB. OUTER BOX

SELECTION OF TREATMENT AREAS: Determine areas where rats or mice will most likely find and consume the bait. Generally, these are along walls, by gnawed openings, in or beside burrows, in corners and concealed places, between floors and walls, or in locations where rodents or signs of rodents have been seen. Remove as much alternative food as possible. Use tamper-resistant bait stations wherever necessary (see **"IMPORTANT:"**).

APPLICATION DIRECTIONS:
The amount of bait contained in the trays in this box is unlikely to be sufficient to kill more than 3 to 12 rats. More than one box may be needed to control larger infestations.

To Control Norway and Roof Rats: Place 1 - 4 bait trays per placement. Space placements at intervals of 15 - 30 feet in infested areas. If trays are not fed for 5 consecutive days, relocate them to other places where rodent activity exists and where placements consistent with the requirements of this label can be made. Maintain an uninterrupted supply of fresh bait for at least 10 days.

To Control House Mice: Open tray and apply 1/4 - 1/2 oz. (1 - 2 level tablespoons) of bait at 8 to 12 foot intervals in infested areas. Larger placements (up to 2 ounces) may be needed at points of extremely high mouse activity. Maintain a supply of fresh bait for at least 15 days.

Check bait locations every 2 days for signs of feeding. Replenish bait if more than 1/2 of the original amount has been removed by rodents. Replace contaminated or spoiled bait immediately if rodent activity is still evident. If trays are not fed from for 5 consecutive days, relocate them to other places where rodent activity exists and where placements consistent with the requirements of this label can be made. Collect and dispose of all dead animals and leftover bait properly.
To prevent reinfestation, limit sources of rodent food, water and harborage as much as possible. If reinfestation does occur, repeat treatment. Where a continuous source of infestation is present, establish permanent bait stations and replenish as needed.

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12 OZ BOX AND 3 LB. OUTER BOX

PRECAUTIONARY STATEMENTS:
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
CAUTION: May be harmful or fatal if swallowed. This material may reduce the clotting ability of the blood and cause bleeding. Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

FIRST AID **Have label with you when obtaining treatment advice.**	
If swallowed by human	• Call a Poison Control Center, doctor, or 1-800-228-4722 immediately for treatment advice. • Do not induce vomiting unless told to do so by the poison control center or doctor.
If swallowed by pet or animal	• Call a veterinarian immediately for treatment advice.

NOTE TO PHYSICIAN AND VETERINARIAN

This product may reduce the clotting ability of the blood and cause hemorrhaging. The anticoagulant action of this product may produce prolonged prothrombin times for 20 to 30 days after exposure. If poisoning occurs, intramuscular and oral administration of Vitamin K_1 are indicated, as in poisoning from overdose of dicumarol (bishydroxy coumarin). **FOR HUMAN CASES:** Vitamin K_1 is antidotal at doses of 10 to 20 mg (not mg/kg). Repeated treatments may need to be given for up to 30 days (based on monitoring of prothrombin times). In severe cases, blood transfusions may be necessary. **FOR ANIMAL CASES:** Contains Brodifacoum, an anticoagulant with a half-life in the dog of 1 - 4 days. For dogs that have ingested or that are suspected of having ingested Brodifacoum, and/or have obvious poisoning symptoms, such as bleeding or have lowered prothrombin times, give Vitamin K_1 as follows: Vitamin K_1 is antidotal at 5 mg/kg intramuscularly. Oral Vitamin K_1 should be given for up to 30 days at 5 mg/kg (based on monitoring of prothrombin times). In severe cases blood transfusions may be necessary.

ENVIRONMENTAL HAZARDS: This product is toxic to fish, birds and wildlife. This product can pose a secondary hazard to birds of prey and mammals. Do not apply directly to water, or to areas where surface water is present or to inter-tidal areas below the mean high-water mark. Dogs and other predatory and scavenging mammals might be poisoned if they feed upon animals that have eaten this bait.

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12 OZ BOX AND 3 LB. OUTER BOX

STORAGE AND DISPOSAL

STORAGE: Store only in original container, in a dry place inaccessible to children and pets.

DISPOSAL: If empty: Do not reuse empty container. Place in trash or offer for recycling if available.

If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

NOTICE TO BUYER AND USER: Buyer and User assume all responsibility for safety and risk associated with any use not in accordance with directions. SELLER SHALL NOT BE LIABLE FOR CONSEQUENTIAL, SPECIAL OR INDIRECT DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT AND SELLER'S SOLE LIABILITY AND BUYER'S AND USER'S EXCLUSIVE REMEDY SHALL BE LIMITED TO THE REFUND OF THE PURCHASE PRICE.

Distributed by: Reckitt Benckiser Inc. Wayne, NJ 07470

Questions? Comments? Call 1-800-228-4722

EPA Reg. No. 3282-81 EPA Est. No. 475-MS-1

MADE IN THE USA

SATISFACTION GUARANTEED OR YOUR MONEY BACK

d-CON BAITS: KILLING RATS AND MICE IN AMERICA FOR 50 YEARS

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3 OZ. BAIT TRAY

(GOOD HOUSEKEEPING SEAL)

Ready To Use Bait Tray

d-CON®
READY MIXED BAITBITS

KILLS RATS AND MICE

Rats and House Mice may consume a lethal dose in one feeding with first dead rodents appearing 4 or 5 days after feeding begins.

Keep out of reach of children.
CAUTION: May be harmful or fatal if swallowed.
Read additional precautionary statements on back panel.

ACTIVE INGREDIENT:
Brodifacoum 3-[3-(4'-bromo-{1,1'-biphenyl}-4-yl)-1,2,3,4-tetrahydro-1-naphthalenyl]-4-hydroxy-2H-1-benzopyran-2-one.....0.005%
INERT INGREDIENTS: 99.995%

TOTAL 100.000%

NET WEIGHT 3 OZ. BAIT TRAY (85g)

---

d-CON: Solving America's Rodent problems for over 50 years

SATISFACTION GUARANTEED OR YOUR MONEY BACK

3 OZ. BAIT TRAY

Kills Warfarin-Resistant Norway Rats and Warfarin-Resistant House Mice.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.
Read the entire label on the outer package before using this product.
It is illegal to sell these bait trays individually.

PRECAUTIONARY STATEMENTS:

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: May be harmful or fatal if swallowed. This material may reduce the clotting ability of the blood and cause bleeding. Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Place bait in areas not accessible to children, pets, domestic animals or wildlife or in tamper-resistant bait boxes.

FIRST AID **Have label with you when obtaining treatment advice.**	
If swallowed by human	• Call a Poison Control Center, doctor, or 1-800-228-4722 immediately for treatment advice. • Do not induce vomiting unless told to do so by the poison control center or doctor.
If swallowed by pet or animal	• Call a veterinarian immediately for treatment advice.

NOTE TO PHYSICIAN AND VETERINARIAN

This product may reduce the clotting ability of the blood and cause hemorrhaging. The anticoagulant action of this product may produce prolonged prothrombin times for 20 to 30 days after exposure. If poisoning occurs, intramuscular and oral administration of Vitamin K_1 are indicated, as in poisoning from overdose of dicumarol (bishydroxy coumarin). **FOR HUMAN CASES:** Vitamin K_1 is antidotal at doses of 10 to 20 mg (not mg/kg). Repeated treatments may need to be given for up to 30 days (based on monitoring of prothrombin times). In severe cases, blood transfusions may be necessary. **FOR ANIMAL CASES:** Contains Brodifacoum, an anticoagulant with a half-life in the dog of 1 - 4 days. For dogs that have ingested or that are suspected of having ingested Brodifacoum, and/or have obvious poisoning symptoms, such as bleeding or have lowered prothrombin times, give Vitamin K_1 as follows: Vitamin K_1 is antidotal at 5 mg/kg intramuscularly. Oral Vitamin K_1 should be given for up to 30 days at 5 mg/kg (based on monitoring of prothrombin times). In severe cases blood transfusions may be necessary.

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3 OZ. BAIT TRAY

ENVIRONMENTAL HAZARDS: This product is toxic to fish, birds and wildlife. This product can pose a secondary hazard to birds of prey and mammals. Do not apply directly to water, or to areas where surface water is present or to inter-tidal areas below the mean high-water mark. Dogs and other predatory and scavenging mammals might be poisoned if they feed upon animals that have eaten this bait.

STORAGE AND DISPOSAL

STORAGE: Store only in original container, in a dry place inaccessible to children and pets.

DISPOSAL: If empty: Do not reuse empty container. Place in trash or offer for recycling if available.

If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

Distributed by: Reckitt Benckiser Inc. Wayne, NJ 07470

Questions? Comments? Call 1-800-228-4722

EPA Reg. No. 3282-81 EPA Est. No. 475-MS-1

MADE IN THE USA

SATISFACTION GUARANTEED OR YOUR MONEY BACK

d-CON BAITS: KILLING RATS AND MICE IN AMERICA FOR 50 YEARS

IRB BRANCH REVIEW - TSS

Record Number(s)

3282-65: D287565
3282-66: D287571
3282-74: D287572
3282-81: D287573

1/13/03 2/2/04

IN _____ OUT _____

EFFICACY

as above

FILE OR REG. NO. _____

PETITION OR EXP. PERMIT NO. _____

DATE DIV. RECEIVED 1/13/03

DATE OF SUBMISSION 11/26/02

DATE SUBMISSION ACCEPTED 1/13/03

TYPE PRODUCTS(S): I, D, H, F, N, R,x S

DATA ACCESSION NO(S) MRID## 458121-06, -07, -08, -09, -10, -11, -12, -13

PRODUCT MGR. NO. 07/PRB (Eagle-Kunst)

PRODUCT NAME(S) various d-Con Brodifacoum products (see next page)

COMPANY NAME Reckitt Benckiser

SUBMISSION PURPOSE product reregistration

CHEMICAL & FORMULATION 0.005% Brodifacoum dry bait products

Efficacy Review: d-CON® MOUSE PRUFE II, 3282-65
d-CON PELLETS GENERATION II, 3282-66
d-CON® BAIT PELLETS II, 3282-74
d-CON READY MIXED GENERATION II, 3282-81
Reckitt Benckiser, Inc.
Wayne, NJ 07474

200.0 INTRODUCTION

THIS REVIEW DISCUSSES CONFIDENTIAL BUSINESS INFORMATION (CBI). DO NOT DISCLOSE CBI TO THIRD PARTIES OR TO ANYONE LACKING PROPER CLEARANCES. DUE TO CHANGES IN OWNERSHIP OF THESE PRODUCTS AND HISTORICAL PROBLEMS WITH FORMULATIONS (DISCUSSED BELOW) IT COULD BE ARGUED THAT THE CURRENT REGISTRANT IS A THIRD PARTY FOR SOME DATA CONSIDERED HERE.

200.1 Uses

3282-65 is a 0.005% Brodifacoum dry bait in 1.5-oz or 3.0-oz wedge-shaped cardboard boxes conditionally registered for indoor use only

> to control house mice in homes, industrial, commercial, agricultural buildings.

3282-66 is a 0.005% Brodifacoum dry bait conditionally registered to control Norway rats, roof rats, and house mice

> in and around homes, industrial, commercial, agricultural and public buildings ... in transport vehicles (ships, trains, aircraft) and in and around related port or terminal buildings.

3282-74 is a 0.005% Brodifacoum dry bait in 1-oz (28-g) placepacks conditionally registered to control Norway rats, roof rats, and house mice

> in and around homes, industrial, commercial, agricultural and public buildings ... also ... in transport vehicles (ships, trains, aircraft) and in and around related port or terminal buildings.

3282-81 is a 0.005% Brodifacoum dry bait in 3-oz bait trays conditionally registered to control Norway rats, roof rats, and house mice

> in and around homes, industrial, commercial, agricultural and public buildings ... also ... in transport vehicles (ships, trains, aircraft) and in and around related port or terminal buildings.

200.2 Background Information

For 3282-65, see efficacy reviews of 12/23/80, 6/5/81, 12/22/87, 8/1/88, 8/11/89, 6/7/90, 6/13/90, 7/11/90, 9/4/90, 3/19/91, 2/1/96, 5/27/99, 1/4/00, and 7/23/01, along with other information in this product's jacket. 3282-65 was registered on 11/6/81 to The d-Con Company, Inc., of Montvale, NJ. As with the other products considered in this review, the ownership of 3282-65 has been transferred several times with no change in registration number. Its current labeling was accepted by EPA on 1/29/02.

For 3282-66, see efficacy reviews of 12/23/80, 6/5/81, 8/16/88, 7/15/88, 12/29/88, 5/14/90, 7/16/90, 1/30/96, 1/12/98, and 1/6/00, along with other information in this product's jacket. 3282-66 was registered on 11/18/81. The current labeling for 3282-66 was "ACCEPTED" by IRB on 1/5/99. See efficacy review of 1/6/00 for a discussion of the use of "graphics" on this product's labeling.

For 3282-74, see efficacy reviews of 12/22/87, 8/1/88, 8/11/89, 11/30/89, 11/17/92, 4/12/93, 11/10/93, 12/15/94, 5/25/99, 1/7/00, 7/23/01, and 5/29/03, along with other information in the product's jacket. See EPA's letter of 1/29/02 which "ACCEPTED" this product's current labeling (after much wrangling, as is recounted in past efficacy reviews and correspondence). This product was registered on 1/16/86. Via a letter of 10/16/01, Reckitt Benckiser (hereafter at times "Reckitt" or "RB") officially changed the name of this product from "d-CON LIM-N8 RAT KILLER" to "d-CON BAIT PELLETS II". RB's predecessor in product ownership (Reckitt & Colman) had used the latter name as an alternative brand since adding it by "Notification" on 5/25/93.

For 3282-81, see efficacy reviews of 1/18/89, 7/16/90, 10/15/90, 1/30/96, 5/25/99, and 1/7/00, along with other information in this product's jacket. This product was initially registered on 2/1/89. "Current" labeling was "ACCEPTED with COMMENTS" on 1/28/99. It seems from the jacket for 3282-81 that neither Reckitt and Colman (R&C) nor RB submitted final printed labeling in response to EPA's letter of 1/28/99. They also did not submit revised labeling in response to EPA's letters of 7/1/99 and 7/5/00. See efficacy reviews of 5/25/99 and 1/7/00 for more on this topic.

See also the Reregistration Eligibility Decision (RED) issued for the Rodenticide Cluster, which includes Brodifacoum and 5 other compounds. That document was reported as "signed" in FY '97 but was not sent to registrants until August of 1998. For reasons upon which this review will not elaborate, applications to reregister products subject to the Cluster RED have only relatively recently been submitted to SRRD's Product Reregistration Branch (PRB).

This review addresses various items submitted or cited in connection with RB's attempts to reregister these products. PRB has routed the following items pertaining to these products for efficacy review:

1. RB's letter dated 11/26/02 pertaining to all 4 products;

2. a letter of 11/6/02 from Rich Lotstein of Syngenta Crop Protection, Inc., providing a "qualified" "authorization" for use of the report assigned "MRID Number 00042578" to support claims of effectiveness of the 4 products against Warfarin-resistant house mice.

3. a Confidential Statement of Formula (CSF) for 3282-65 dated "11/25/02";

4. a proposed revised label for 3282-65 for "1.5 oz and 3.0 oz sizes" received by OPP on "12-06-02";

5. a proposed revised label for 3282-65 for "6oz (170g) Outer Carton (4/1.5oz wedges)" stapled to the other label for 3282-65 marked received by OPP on "12-06-02";

6. two copies of a "**DATA MATRIX**" dated "11/25/02" for 3282-65, with the second copy having the names of studies, study protocol numbers, and MRID numbers blacked out;

7. a Confidential Statement of Formula (CSF) for 3282-66 dated "11/25/02";

8. a proposed revised label for 3282-66 for a "12 OZ BOX" received by OPP on "12-06-02";

9. a proposed revised label for 3282-66 for a "3 OZ. BAIT TRAY" stapled to the other label for 3282-66 marked received by OPP on "12-06-02";

10. two copies of a "**DATA MATRIX**" dated "11/25/02" for 3282-66, with the second copy having the names of studies, study protocol numbers, and MRID numbers blacked out;

11. a Confidential Statement of Formula (CSF) for 3282-74 dated "11/25/02";

12. a proposed revised label for 3282-74 for a "**1.0 oz - Bait Pack (for Mice)**" received by OPP on "*12-06-02*";

13. a proposed revised label for 3282-74 for a "**1.0 oz Bait Pack (for Mice and Rats)**" stapled to the mouse "**Bait Pack**" label for 3282-74 marked received by OPP on "*12-06-02*";

14. a proposed revised label for 3282-74 for a "**6/1.0 oz Bait Pack Outer Box**" stapled to the mouse "**Bait Pack**" label for 3282-74 marked received by OPP on "*12-06-02*";

15. a proposed revised label for 3282-74 for a "**20/1.0 oz Bait Pack Outer Box**" stapled to the mouse "**Bait Pack**" label for 3282-74 marked received by OPP on "*12-06-02*";

16. two copies of a "**DATA MATRIX**" dated "*11/25/02*" for 3282-74, with the second copy having the names of studies, study protocol numbers, and MRID numbers blacked out;

17. a Confidential Statement of Formula (CSF) for 3282-81 dated "**11/25/02**";

18. a proposed revised label for 3282-81 for a "**12 OZ AND 3 LB. BOX**" received by OPP on "*12-06-02*";

19. a proposed revised label for 3282-81 for a "**3 OZ. BAIT TRAY**" stapled to the other label for 3282-81 marked received by OPP on "*12-06-02*";

20. two copies of a "**DATA MATRIX**" dated "*11/25/02*" for 3282-81, with the second copy having the names of studies, study protocol numbers, and MRID numbers blacked out;

21. an efficacy report assigned MRID# 458121-06;

22. an efficacy report assigned MRID# 458121-07;

23. an efficacy report assigned MRID# 458121-08;

24. an efficacy report assigned MRID# 458121-09;

25. an efficacy report assigned MRID# 458121-10;

26. an efficacy report assigned MRID# 458121-11;

27. an efficacy report assigned MRID# 458121-12;

28. an efficacy report assigned MRID# 458121-13:

29. a document entitled "**Explanation for reports 13760.4102 and 13760.4109: The Efficacy of anticoagulant Dry Bait Rodenticide Using Feed Choice Test with Albino Laboratory Rats (*Rattus norvegicus*, Wistar)**"; and

30. a document entitled "**Explanation for reports 13760.4101 and 13760.4108: The Efficacy of Anticoagulant Dry Bait Rodenticide Using Feed Choice Test with Albino Laboratory Mice (*Mus musculus, CD1*)**".

According to RB's letter of 11/26/02 (signed by former RB employee Sean McNear),

> All four products have the same formulation (4-PA-165). All four products share the same efficacy reports and the product chemistry reports.

That having been said, it is clear from the "Explanation" documents that two different pellet diameters (3/32" and 3/16") were used in the efficacy studies.

201.0 DATA SUMMARY

201.1 Formulations

The CSF of 11/25/02 for 3282-65 describes a [redacted] formulation which lists similarly named ingredients and nominal concentrations for them as those that appear on the last CSF (dated "6/29/89") accepted for 3282-65. However, broader ranges in certified limits are proposed on the pending CSF for every ingredient except the dye component [redacted] on the proposed revised one); and new sources are listed for all ingredients. [redacted]

The certified limits proposed for the active ingredient are 0.004-0.0065%, a much broader range than the 0.005-0.006% that appears on the CSF of 6/29/89 which was submitted as part of [redacted] The registrant (then called Lehn & Fink) proposed such expansion of certified limits for Brodifacoum in 1991, confessing to an inability to formulate baits within the tighter range. L&F were told (EPA's letter of 7/9/91) that they would have to document their actual results because the limits being proposed (CSF dated "2/7/91") were, on percent bases, "beyond the standard ones of 40 CFR 158.175(b)(2)". There is no evidence in the jacket for 3282-65 that L&F or any subsequent registrant for that product provided such documentation, but L&F did slip a CSF dated "6/14/91" with the expanded certified limits by OPP via a notification (ostensibly to add an alternate supplier for the inert ingredient [redacted]

A CSF dated "October 6, 1999" for an "Alternate Formulation" for 3282-65 was found by EPA not to be acceptable for 3282-65 because EPA does not allow alternate formulations for rodenticide baits (excepting dye substitutions with efficacy data support) and because the efficacy data submitted to support the CSF of 10/6/99 were not acceptable as submitted. The CSF of 10/6/99 claimed a different source of Brodifacoum [redacted] and various other inert ingredients.

The CSF of 11/25/02 for 3282-66 describes a [redacted] formulation identical to that described by the CSF of 11/25/02 for 3282-65. The formulation history for 3282-66 also is similar to that for 3282-65, with the CSF of record being dated "2/17/89", the first CSF with expanded certified limits for Brodifacoum being dated "2/7/91", and the rejected CSF for an "Alternate Formulation" being dated "October 6, 1999". For 3282-66, there is clear evidence that the CSF dated "2/7/89" was accepted (EPA's letter of 12/29/89), that additional data were required before the expanded certified limits could be accepted (EPA's letter of 7/9/91), and that the CSF of 10/6/99 was rejected for 3282-66. The jacket for 3282-66 also contains a "NOTIFICATION" dated "6/14/91" concerning an alternate supplier of "[redacted] but no CSF of that date.

The CSF of 11/25/02 for 3282-74 also lists the same ingredients, suppliers, nominal concentrations, and certified limits as are listed on the CSFs of 11/25/02 for 3282-65 and 3282-66. 3282-74 originally was formulated differently from 3282-65 and 3282-66. The last CSF submitted which bore the original formulation ([redacted] is the CSF dated "2/7/91". The CSF of 2/7/91 was reviewed and nearly accepted (EPA's letter of 7/9/91) but for the need to justify the proposed expanded certified limits for Brodifacoum.

While the CSF of 2/7/91 for 3282-74 was being reviewed, L&F's Paul Kruger submitted a new CSF (dated "3/15/91" for 3282-74, explaining that he "had inadvertently included an outdated" CSF (that of 2/7/91) in his submission of 2/22/91. The CSF of 3/15/91 describes a formulation like that described by the CSF of 2/7/91 for 3282-66, implying that L&F had changed the formulation for 3282-74 (unilaterally) some time previously. The jacket for 3282-74 contains no record of a review or a letter from EPA regarding the CSF of 3/15/91 which, I infer, was used subsequently (and probably previously) for 3282-74. The efficacy data used to support 3282-74 were submitted in 1989, so the composition of the test material used in those studies is not obvious. (As different efficacy data were submitted for 3282-65 and 3282-74, the company may have felt at the time that the two products differed [by more than particle size].)

R&C also submitted a CSF dated "October 6, 1999" for an "Alternate Formulation" for 3282-74, which IRB rejected for reasons similar to those indicated above for the similarly dated CSF submitted for 3282-65. However, that CSF was "**SCANNED**" by OPP on "SEP 3 2003", probably because a product chemist had prematurely written "*Acceptable Somi Malak 4/17/00*" on it. As RB has proposed a formulation like that on its CSF of "3/15/91" (which we appear never to have accepted), the historical problems would be resolved (except for any violations) if the CSF of 11/25/02 were accepted.

The current CSF for 3282-81 appears to be the one dated "12/5/88" because: (1) the CSF dated "2/7/91" was not accepted for want of analytical data (as with the other products); (2) the CSF dated "6/14/91" and submitted via "NOTIFICATION" ostensibly to report an alternate supplier of [redacted] was not addressed by OPP and did not correspond to the CSF of record; (3) and the CSF dated "October 6, 1999" was rejected for the same reasons given for the CSFs of that date for the other 3 products. Probably because "*NOT ACCEPTED SEE LETTER DATED 7/5/00*" was written above "*Acceptable Somi Malak 4/17/00*", it was the CSF of 6/14/91 rather than that of 10/6/99 (or the correct one dated "12/5/88") that mistakenly was "**SCANNED**" by OPP on "SEP 3 2003".

201.2 Efficacy Data

Effectiveness Against Warfarin Resistant Commensal Rodents

To support retention of claims of effectiveness against Warfarin-resistant house mice, Reckitt Benckiser has cited "00042578", as Syngenta's Lotstein had said that they could. (There seems not to be a citation concerning control of Warfarin-resistant Norway rats, which has been demonstrated for 0.005% Brodifacoum baits.) The number "00042578" does not look like a valid MRID or Accession number, as the former should have a hyphen between the 6th and 7th digits and the latter were only 6 digits long. Nevertheless, information that Lotstein mentions along with the number suggest a document with authors' names consistent with 3 people who were researching Warfarin-resistance and/or Brodifacoum at the time (1980) of the publication.

I looked back into my record of reviews for the initial Brodifacoum applications and early registrations and found that I had accepted reports relevant to the claim that 0.005% Brodifacoum bait is effective against Warfarin-resistant house mice collected in the U.S. That report was assigned the Accession No. 243576. I obtained a faint blow-back copy of the item recently from Microfiche and confirmed that the subject matter contained in it was, as I had indicated in my efficacy review of 12/17/80, which was linked to former registration numbers 10182-38, 10182-39, 10182-40, 10182-41, 10182-43, and 10182-44. The data subsumed under that accession number still would be acceptable for 0.005% Brodifacoum baits that pass our other efficacy data requirements.

On 1/29/04, I requested a blow-back of "00042578" as an MRID number. The item assigned that number was the same report that had been assigned Accession No. 243576 when it was submitted in 1980. As only 10 subjects were used in the study assigned those numbers, it would have been inadequate, standing alone to support the claim "kills Warfarin-resistant house mice."

In the efficacy review of 10/12/78, I reviewed 4 volumes of efficacy data which included reports on the effectiveness of 0.005% Brodifacoum baits against Warfarin-resistant Norway rats, roof rats, and house mice. Those reports were assigned the Accession numbers 234657, 234658, 234659, and 234660. I concluded that data in the material that I reviewed at that time were adequate to support "The claim 'kills warfarin resistant rats and mice.'" My review of 10/12/78 referenced the various reports included in the 4 volumes according to document numbers ("1H" to "76H") but did not link those numbers to specific Accession numbers. Consequently, I obtained Microfiche blow-backs of all 4 volumes.

My review of 10/12/78 indicated that information relevant to claims for control of Warfarin-resistant commensal rodents could be found in document numbers "1H", "2H", "3H", "4H", "5H", "61H", "62H", "64H", and "65H" (the last of these references should have been "63H").

The Accession number for items "1H" to ""5H" is 234657. "1H" and "2H" are summary documents prepared by the applicant for registration, ICI Americas. (Syngenta likely would own these data now, although the submission is more than 25 years old at this point. Whether that company could rightfully claim entitlement to compensation for such data by submitting them now under their own banner is not clear to me.) "3H" and "4H" address Warfarin-resistance in wild-type Norway rats, roof rats, and house mice from the United Kingdom using a screening method similar to what EPA accepts but with different procedures for challenging the rodents with Brodifacoum than would be used here. Item "5H" reports results of field trials conducted in areas in the U.K. where pockets of resistance to Warfarin had been noted.

Items "61H", "62H", "63H", and "64H" pertain to laboratory efficacy trials conducted against commensal rodents of U.S. origin which, according to screening results, were resistant to Warfarin and sometimes also to Pival, another first-generation anticoagulant. These items are found among many other documents in the volume assigned Accession no. 234660.

"61H" describes work directed by Stephen Frantz at New York State's rodent laboratory in Troy, NY. He obtained 95% kill in a standard laboratory efficacy test (much like Protocol 1.203, see below) of 20 Norway rats previously screened for resistance to Warfarin (6 days no-choice on 0.005% Warfarin diet) with bait acceptance being 37%.

"62H" describes research directed by William Jackson at Bowling Green (OH) State University. Jackson's Norway rats had survived challenges with Warfarin at 0.005% no-choice for 6 days and, after a 30-day cleansing period, a similar challenge with the anticoagulant Pival. After another cleansing period, Jackson gave the 7 rats (4 males, 3 females) that made it to that point 6 days of no-choice exposure to a 0.005% Brodifacoum diet, after which they all died. Due to the small number of subjects and the lack of a challenge diet in the Brodifacoum trial, this study, by itself, would have been insufficient to support a claim of effectiveness against Warfarin-resistant Norway rats.

"63H" describes research by Lawrence Lewallen of the Health Department in Fresno, CA. Lewallen had 4 roof rats survive 12-day challenges on 0.025% Warfarin and 0.025% Pival, with intervening cleansing periods. These animals were 3% of those that had initially been put to these challenges. After another cleansing period, Lewallen exposed the 4 survivors to a choice between an 0.005% Brodifacoum diet (Talon pellets) and "EPA meal" (presumably standard rat and mouse challenge diet). All 4 roof rats died within 13 days.

"64H" describes work with wild-type house mice of Buffalo, NY, origin conducted by Frantz. These were challenged with no-choice exposure to a 0.025% for 21 days. Of the 29 mice subjected to the procedure, 21 survived; and Frantz selected 10 of them for use in a 3-day choice test involving 0.005% Brodifacoum bait and "EPA meal". All 10 mice died. Bait acceptance was 55%.

Collectively, the items in Accession numbers 234660 and 243576 support claims that 0.005% Brodifacoum baits control Warfarin-resistant house mice and Norway rats in the U.S. and suggest that the same may well be true for Warfarin-resistant roof rats. The citation of MRID number 00042578 is insufficient by itself to support the claim for controlling Warfarin-resistant house mice.

The efficacy studies submitted to support reregistration of these products are cited and discussed below according to target species.

Commensal Rats

Baroch, J. (2002a) Norway rat (*Rattus norvegicus*) Acute Dry Bait Using Test Substance Formula 4-PA-165 (Brodifacoum 50 ppm): one-day test. Unpublished report, Genesis Laboratories, Inc., Wellington, CO, 89 pp.

MRID# 458121-10

Baroch (2002a) reports having run this study using "Formula Number: 4-PA-165" as the test material. According to Baroch (2002a), RB provided prepared bait to Genesis Laboratories and was responsible for the chemical analysis of the test material. In past instances in which RB has documented bait formulations, codes of the form shown for "4-PA-165" actually have referred to bait mixtures and are accompanied by references to notebook pages where information concerning the preparing of a specific bait batch is provided. It seems that a code such as "4-PA-165" pertains to the proportions of ingredients in a bait so that the code could be used for baits of a common composition but different particle sizes.

"Appendix D8" ("Page 85 of 89" in the Baroch, 2002a, report) consists largely of a "Reckitt Benckiser Analytical Services GLP Report" (which is woefully weak in GLP-type documentation). The "Reckitt Benckiser Analytical Services GLP Report" summarizes results of assays of "Samples of Formula # 4-PA-165 Batch # PPO010920 Reference # 811-017" for Brodifacoum concentration. Twelve assay results are listed. These are for the "start", "middle", and "end" of 4 pails into which bait apparently had been loaded. (None of the 4 products covered by this review is sold retail in a container that might be described as a "pail".) The results summarized show the test material to have been 45-51 ppm (i.e., 0.0045-0.0051%) Brodifacoum. These results are within a 0.0045-0.0055% a.i. range and suggest better quality control than L&F claimed that it could attain when seeking to expand the certified limits for these products to 0.0040-0.0065% Brodifacoum. (See relevant discussions above.) Limits of detection are not reported on this "GLP Report".

Baroch (2002a) reports (pp. 51-56) that the challenge diet that Genesis prepared for this bioassay tested negative for Brodifacoum. The reported limit of detection was 0.53 micrograms/gram or 0.53 ppm. The limit of quantitation was 1.88 ppm or about 1/27 of the nominal concentration of Brodifacoum in the test material.

Baroch (2002a) reportedly followed the "one-day" version of OPP Protocol 1.209, the procedure recommended for screening for efficacy anticoagulant baits for which claims for control in a single night's feeding are sought. According to this protocol, acclimatized groups of singly-caged rats (at least 10/gender) are to be exposed to the toxic bait plus OPP rat and mouse challenge diet for one 24-hr period, after which the bait is removed and the subjects' consumption of challenge diet and their general health are to be recorded until the animals die or at least 10 post-exposure days elapse. A 20-animal control group is to be monitored concurrently to the test group but is to be fed only OPP challenge diet for the "exposure" and follow-up periods.

Baroch (2002a) essentially followed those procedures in this study. As Protocol 1.209 recommends, Baroch included a replicate 20-animal test group in the study design. Thus, there were 2 test groups and a control group each comprised of 10 male and 10 female rats. Wistar

strain albino Norway rats were used *in lieu* of wild-type *Rattus norvegicus*. Protocol 1.209 permits such a substitution. Animal weights at the start of the 3-day acclimation period preceding the bait-exposure period are summarized below for the 3 groups of rats.

GROUP	SEX	INITIAL WEIGHTS (g)	
		Mean	Range
Control	Females	243.0	233.3-264.0
	Males	248.9	233.5-266.8
Test "I"	Females	239.6	226.9-252.0
	Males	251.3	242.2-268.8
Test "II"	Females	236.2	215.5-264.2
	Males	247.8	227.6-267.1

These weights and the weight differences between sexes are well within the requirements of Protocol 1.209, and Baroch saw to it that such would be the case.

During the bait exposure period, Baroch (2002a) attempted to balance the effects of feed container position preferences by starting 10 subjects in each test group with jar holding bait on the left side of the cage and the one holding challenge diet on the right, with the other 10 subjects having the two diets deployed in the opposite positions. Twelve hours into the bait-exposure period, the positions of the containers were reversed in each cage.

Results of this study are summarized in Table 1 (Replicate I) and Table 2 (Replicate II). Eighteen of 20 rats died in each test group, thereby meeting the performance criterion of Protocol 1.209. In Replicate I, 5 of the 9 male victims lost weight (1.2-25.7 g), while 4 gained (6.8-32.6 g). The surviving male gained 48.8 g. Replicate I's female victims also included 5 that lost weight (1.2-29.4 g) and 4 that gained (1.0-17.9 g). The female survivor gained 41.5 g. In Replicate II, 2 of the 8 male victims lost weight (0.9-8.8 g), while 6 gained (3.2-39.7 g). The surviving males gained 38.9 g and 60.1 g. Replicate II's female victims included 5 that lost weight (1.7-15.3 g) and 5 that gained (0.7-21.3 g).

All 36 test-group victims were observed at necropsy to show signs consistent with anticoagulant poisoning. None of the 4 survivors displayed overt signs of coagulopathy.

All control group rats survived and gained weight (14.3-81.7 g).

Bait acceptance (percent of all consumption during bait-exposure period that is comprised of challenge diet) was below 30% in both replicates. While the 33% minimum composite bait acceptance criterion that applies in multiple-day exposures to anticoagulant baits does not apply for one-day tests, it is worth noting that all 4 survivors in the 2 test groups reportedly ate 1.0 g or less of the toxic bait and probably survived for that reason. One of the victims also reportedly consumed less than a gram of toxic bait. These 5 animals clearly pulled the composite acceptance figure downward. A 12.5% incidence of marginal feeders is not a good sign for an anticoagulant bait, although it is possible that the 4 survivors and the marginal feeder that died anyway would have accepted the bait better with a longer period of exposure to it.

Test room temperatures during the bioassay ranged from 20-30°C (68-86°F), running well beyond the 20-25°C range specified in Protocol 1.209. The 25°C level was exceeded only on two days 12/22/01 and 12/23/01 (the study was terminated on 12/24/01). The days of excess

temperature were 8 and 9 days after the bait-exposure day, by which time only the 4 ultimate survivors and the one marginal feeder that eventually died were alive in the test groups.

Relative humidity ranged from 11% to 67% during the bioassay. The low figure was observed on 12/23/01, which was around the time of the death of the animal (male #12, Replicate I, that died despite reportedly consuming just 0.3 g of bait. The lowest minimum relative humidity figure reported for any other day was 23%, which was observed on 2 days during the pre-test holding period (prior to the 3-day acclimation period which preceded the bait-exposure day).

In the protocol deviation section of the report (pp. 34-35), Baroch (2002a) notes "occasional swings outside the desired limits" for temperature and relative humidity and states that

> The high temperature and low humidity periods that occurred near the end of the post-exposure period, after all the treated rats that showed symptoms of test substance exposure were dead.

This non-sentence implies that the extreme (for a laboratory) hot-and-dry conditions occurred on 12/23/01 after male #12 died. The notes for that animal on his group's "SMALL MAMMAL DAILY OBSERVATION" form imply that it was found dead on 12/23/01 -- the day *after* the peak in temperature was noted. It is not clear from that information whether the humidity in the lab went down to or close to 11% while that animal still was alive. (Baroch, 2002a, discusses at length procedures for assigning rats periods of survival and giving half-day scores for the day that animal's were found dead. Under that system, male #12's score would have been 8.5, for 8 days post-onset of exposure when he was observed alive plus his presumed survival for part of 12/23/01.)

The Baroch (2002a) trial would be a clearly acceptable study but for the temperature and humidity extremes, especially those on 12/22/01 and 12/23/01 and their possible effects on the health of male #12. I have concluded that the study may be accepted despite that problem, primarily because those most extreme discrepancies only affect the pass/fail status of one of the two replicates.

Before this study can be considered to be applicable for the pending CSFs for and of these d-Con products, the identity of the test material (formulation, form, and particle size) must be documented.

Stafford, J.M. (2002b) 4-PA-165, 3/16-inch diameter pellets: the efficacy of anticoagulant dry bait rodenticide using a feed choice test with albino laboratory rats (*Rattus norvegicus*, WISTAR). Unpublished report, Springborn Smithers Laboratory, Snow Camp, NC and Wareham, MA, 130 pp.

MRID# 458121-07

To the best of my recollection, the Stafford (2002a) study and the other studies attributed to her (discussed below) are the first from Springborn Smithers that I ever have reviewed. In 2001 and 2002, I corresponded with RB and with a Larry Brewer of "Springborn Labs" concerning protocols and procedures for laboratory efficacy tests with rodenticide baits. In electronic and oral communications, I stressed the importance of involving EPA early in Springborn's history of running efficacy studies. In my e-mail of 4/11/02 to Brewer, for example, I noted the following:

> Again, it is extremely important to have your work reviewed by us before you have run a whole bunch of studies. Efficacy trials differ from drug and toxicity trials in significant ways. Although our protocols address many particulars, there still is a learning curve with them; and any mistakes made in the first trial are apt to be repeated until you get feedback from us. Those with whom you have contracted to run rodenticide efficacy trials would be well advised to have your initial efforts put

into review ASAP rather than waiting until they have a complete set of reports for their entire product lines. Note that each study report is to include a narrative of the procedures actually followed, a copy of the protocol that was supposed to be followed, the usual GLP documentation regarding deviations from protocol and quality assurance, reports of analyses of test material and challenge diet for the active ingredient, tabular summaries of results, copies of all raw data sheets, and all other pertinent information. The sponsor of the studies is expected to provide documentation which links the batch of test material to a specific formulation and bait form.

Stafford did much of that, but 6 studies were submitted from her facility. This means that errors made in one of them might well be common to all 6.

"Page 5" of the report identifies "Susan M. Hamel" as a "Technical Report Writer" for this document and shows a signature date for her which precedes Stafford's by 2 days. It is possible that Hamel wrote up the narrative report without having been involved in the study procedures. (The narrative reads in parts as though it is a sort of check-off the elements presented in the copy of Protocol 1.203 that I supplied to Brewer, which the report identifies with the Protocol's initial date of 2/25/74 rather than the date of its current version -- 6/18/91.)

Stafford (or Hamel) describes the test material as "4-PA-165, 3/16-inch diameter pellets, Batch No. B02029A", adding that Reckett indicated that the batch had "a purity of 0.005%". "Page 54" of the Stafford (2002a) report is a "**Reckitt Benckiser** Analytical Services GLP Report" for "Log Number : 020098" and "Formula # 4-PA-165 Batch # B02029A Reference # 811-048B (D-Con Bait Pellets II Kills Rats & Mice)". According to this sheet, 6 samples of this batch (2 samples for each of 3 "prep" numbers) assayed at 50-52 ppm (0.005-0.0052%) Brodifacoum. Such results were at or very close to the nominal concentration of 0.005% Brodifacoum claimed for all 4 products discussed in this review and suggest that the previously "proposed" certified limits of 0.004-0.0065% were too broad.

The bait reportedly "was stored at room temperature" (range not indicated). Stafford (2002a) weighed 20 individual pellets and 10 sets of 5 pellets. The individual pellets averaged 0.24 g (range 0.147-0.291). The groups of 5 pellets averaged 1.26 g (range 1.03-1.39 g).

According to the "**GOOD LABORATORY PRACTICE COMPLIANCE STATEMENT**" page (3),

> routine water contaminant screening analyses for pesticides, PCBs and toxic metals were conducted using standard U.S. EPA procedures by GeoLabs, Inc., Braintree, Massachusetts. Food contaminant screening analyses for pesticides, PCBs and toxic metals were conducted using U.S. standard procedures by Purina Mills, Inc., Richmond, Indiana. The OPP challenge diet was prepared following ISO 9002 guidelines by Purina Mills, Richmond, Indiana. The reference substance, brodifacoum, was purchased from a commercial supplier and therefore not characterized under GLPs.

The Brodifacoum mentioned in the paragraph just quoted apparently was the material used to spike samples of challenge diet for recovery analyses. The Brodifacoum was sent to the Springborn Smithers facility in Wareham, MA where it was

> stored in the original containers in a dark, ventilated cabinet at room temperature and ... used to prepare calibrations standards during the analytical phase of the study.

Stafford (2002a) states that the challenge diet was "maintained at -18 °C or below from receipt until use" but does not state whether Purina Mills froze it after preparation and/or whether it was or remained frozen during shipment. Purina Mills reportedly found a "representative

sample" of the challenge diet to be free of "pesticides, PCBs and toxic metals." The Springborn Smithers facility in Snow Camp, NC, reportedly over-nighted frozen samples of challenge diet to their Wareham, MA, facility for use in chemical assays.

In 3 trials each with challenge diet samples spiked to be 4.99, 25.0, or 59.9 ppm, Springborn (Wareham) obtained a mean recovery of 78.4% (SD=5.25%) and a limit of quantitation (LOQ) of 0.561 mg/kg. The 3 "Control" samples (unspiked challenge diet) all were below the LOQ. These figures come from "**APPENDIX II - ANALYTICAL METHODOLOGY**" (pp. 42-52 of the Stafford (2002a) report. That report's "Table 1." (p. 23) shows 2 analyses of challenge diet being below an LOQ of 0.559 ppm.

The bioassay was run at the Springborn Smithers facility in Snow Camp, NC, but the data reportedly are stored at Wareham, MA. (That situation would make for incomplete, or expensive two-site, laboratory audits.) Stafford (2002a) reports having followed "OPP Protocol Guideline 1.203", or an approximation thereof entitled "Springborn Smithers Laboratories Protocol No.: 11080/FIFRA/Rat Efficacy", adding that

> The methods described in this protocol meet the requirements specified in U.S. Environmental Protection Agency's Test Guideline (Draft) OPP 1.203, Standard Norway Rat/Roof Rat Anticoagulant Dry Bait Laboratory Test Method (U.S. EPA, 1974).

The protocol by that name that I supplied was the version of "6-18-91".

For this study, Springborn Smithers used 60 Wistar strain laboratory Norway rats as subjects. The rats were housed individually in stainless steel hanging, mesh-bottom cages with "a bottom surface area of 651.7 cm^2" (equivalent to 10 inches square), thus preventing the animals from stretching out their tails but still being above the lower limit (500 cm^2) on cage size indicated in Protocol 1.203.

The animals were maintained on a 12:12-hr light:dark cycle at 47 foot candles during the "light" phase. Laboratory temperatures reportedly ranged from 19-28°C (66-82°F), thus running outside the specified range of 20-25°C (68-77°F). In a "**PROTOCOL DEVIATION**", Stafford (2002a) states that the upper extreme was reached

> due to a temporary failure of the cooling system which was repaired by noon the next day. This temperature deviation did not adversely affect the results of this study since control performance was acceptable.

While it is reassuring that unpoisoned animals did not keel over when the temperature went up a bit, the conclusion that the exposed animals were not affected by temperature changes is somewhat overdrawn. Raw data sheets on pages 65 and 66 of the report indicate that the breakdown was discovered on 5/29/02 and that the repair was completed on the following day.

Relative humidity in the facility reportedly ranged from 50-60% and, like temperature, was continuously monitored. While outside the 50-55% range specified in Protocol 1.203, the range reported by Stafford is close to that range (and a bit surprising given the air conditioning breakdown). Pages 65 and 66 of the report show single handwritten entries for relative humidity for the study period (5/14-6/10/02). Those entries do indeed range from 50% to 60%. (That range is much tighter than the one reported by Baroch, 2002a).

Rats were acclimated to laboratory conditions and maintained on local well water and a commercial laboratory diet (which Purina Mills had "analyzed ... for the presence of pesticides, PCBs and toxic metals") for 7 days. The well water also reportedly was free of "pesticides, PCBs and toxic metals."

The rats were randomly assigned to one of 3 groups: the control group and 2 test groups. Each group consisted of 10 males and 10 females, all caged individually. Female subjects reportedly averaged 210.1 g and males 229.5 g "one day prior to test initiation." Within groups, the breakdown in initial body weights was as shown below.

GROUP	SEX	INITIAL BODY WEIGHTS	
		Mean	Range
Control	Males	231.1	205.5-242.3
	Females	210.5	168.1-229.0
Rep. 1	Males	235.2	211.2-259.5
	Females	214.2	197.2-227.3
Rep. 2	Males	222.2	191.4-243.6
	Females	205.5	156.9-229.2

Differences between sexes in initial body weights were well within the requirements of Protocol 1.203.

After the end of the acclimation period, test-group subjects were exposed for 15 days or until death, if sooner, to a dietary choice between the test material and EPA challenge diet. The diets were placed in 46-g amounts (or more?) in separate "feeders" which were deployed "at the front of each cage". Control-group animals received 46 g of challenge diet in each of the 2 feeders deployed in their cages. Stafford (2002a) notes that "positions of the feeders were reversed daily" and that "feed measurements were to the nearest 0.1 g."

With respect to spillage of diets, Stafford (2002a) states that

> Catch pans were placed beneath each cage, so that spill could be accounted for in feed consumption. The animals did not spill Challenge Diet, but only the larger bait pellets which were easily carried about. Therefore only bait spill was recorded.

Following the bait-exposure period, surviving animals were maintained on challenge diet and observed for 5 more days, as prescribed in Protocol 1.203.

Springborn personnel reportedly looked in on subjects 1-3 times/day while keeping "Human activity within the animal test room ... to the necessary minimum."

Results in the test group are shown in Tables 3a, 3b, and 4. These data indicate that 1 rat (a male) survived in the Replicate 1 test group (95% mortality) while all died in Replicate 2 (100% mortality). These results exceed Protocol 1.203's criterion of 90% mortality. Symptoms of toxicosis (e.g., bleeding at ear-tag site, other external hemorrhaging, piloerection) were noted in most test-group subjects prior to their deaths.

The male victims in Replicate 1 included 4 that lost weight (2.9-40.0 g) and 5 that gained (0.3-73.5 g), while the survivor gained 41.6 g. Five of the female victims in Replicate 1 lost weight (1.1-40.1 g), and 5 gained (0.9-15.7 g). In Replicate 2, 6 males lost weight (9.6-37.8 g); 4 males gained (9.7-25.0 g); 5 females lost (9.1-39.6 g); and 5 females gained (5.6-46.5 g).

All subjects in the control group reportedly survived and gained weight (31.4-64.3 g for males; 21.3-61.0 g for females). These data suggest that the control-group animals were in good health and that the challenge diet fed to them was of adequate quality.

Table 3a shows data on feed consumption by the Replicate 1 test group as calculated from the raw data sheets which comprise pages 80-103 in "**APPENDIX III**" of Stafford's (2002a) report. On those pages, data for subjects are presented in cage-number-order -- which made extracting the data very tedious.

Complicating matters further were the facts that Stafford (2002a): (1) presents spillage recovery data on a different set of raw data sheets, which occupy pages 104-109; and (2) that she includes in her calculations negative "consumption" data for instances in which the feed weighed more at weigh-back than when it was presented initially and/or the amount of recovered spillage under an animal's cage, when added to the weight of the feed container at weigh-back, created a number larger than the weight of the loaded container at deployment. In Table 3b, I present the feed consumption results for Replicate 1 as adjusted by Stafford. These data come from pages 121-130 in "**APPENDIX IV - COMPUTERIZED DATA**".

A "**NOTE TO FILE**" dated "*06/17/02*" that appears on page 75 of the report indicate that spilled material was collected daily, put in "sealable plastic bags" which were "not fully" sealed so as "to permit the spilled bait to dry", and "weighed at a later date". Although the bags were "labeled with the date of collection and the cage number",

> some of the spill weighed more than the total amount (calculated) removed from the feeder for that day. This occurrence is explained by the fact that the catch pans did not capture 100% of the spill. Some spill fell just outside the edges of the pans and this was collected on the day that each animal died in the respective cages [.] However, this "extra spill" was labeled with the date of the beginning of treatment, since it was impossible to determine the exact date each pellet was spilled. Therefore, a number of the daily spill weights resulted in negative weights for total bait consumed. The total 15-day consumption values for each animal reflect positive values, indicating that these negative numbers "evened out" over the course of the 15-day test. This "evening out" resulted in the same value for total food consumption as if the post-death "extra spill" value had been divided by the number of the days the animal was in the cage and then that amount was added to the daily spill value for the respective cage. The electronic data print-outs provide all values of bait consumption: exact daily values of bait left and bait added, and calculated values for bait used (for chemical use tracking purposes), bait removed, and bait consumed (removed minus spill). Therefore, reviewers will be able to identify the values used in all calculations.

Identifying the values is one thing (and not an easy thing in this case). Having confidence in them is another. In this "**NOTE TO FILE**" Stafford makes a valiant but unsuccessful attempt to turn lemons into lemonade. As there is no way at this point to determine who spilled what. At best the "corrective" effects of including "negative" consumption figures would apply to composite summaries. As animals apparently were randomly assigned to cage numbers, bait spillage outside of catch pans could not even be assigned to a test group let alone to a specific gender or individual rat.

"Extra spill" of challenge diet could not even be assigned to treatment versus control groups if the animals were randomly assigned to cages within racks. Stafford attempts to dismiss spilled challenge diet as a factor with a handwritten note added to the "**NOTE TO FILE**" dated "*06/17/02*". That note reads as shown below.

> *The rats did not appear to spill any of the OPP Challenge Diet, which was of a much finer consistency than the bait pellets. Therefore, OPP spill was not collected.*

In this note, Stafford first says that spill of challenge diet was not evident and later says that it was "*not collected*". Although the two representations are not entirely self-contradictory, they are not fully reconcilable either. That hand-written note is initialed and dated "*JS 7/9/02*", which dates it almost a month after the end of the bioassay and more than 3 weeks after the rest of the **"NOTE TO FILE"** was made.

At this point, I feel that the consumption data reported in this study for bait and challenge diet are suspect. Springborn Smithers would have been well advised (and probably were) to run pilot trials to work out procedural details on matters such as bait spillage. I should note that scattering of challenge diet is a common frustration for technicians who run these studies. Stafford *might* have minimized challenge diet spillage by her use of a "perforated food follower" in each feed container and

> a "deluxe lid" which slightly reduced the top opening of the jar, and prevented the food follower from being removed.

Due to my lack of confidence in the accuracy of either the data in Table 3a or 3b and to the, consequently, unproductive tedium extracting data from raw data sheets as prepared by Springborn Smithers, I present for Replicate 2 (in Table 4) only the results taken from page 130 of **"APPENDIX IV - COMPUTERIZED DATA"**.

Such as they are, the bait acceptance data in Tables 3b and 4 all are below the criterion of 33% acceptance (bait take as a total of all food consumption) which appears in Protocol 1.203. The data in Table 3a are barely above 33% but are highly questionable (as are the data in the other tables). Even if we assumed these data to be correct, the acceptance is generally below 33%. Thus, the data collected in this study do not meet all criteria of the relevant test protocol.

The **"SUMMARY"** portion of the report concludes with the following paragraph:

> While the level of mortality measured in this study verified that the test rats consumed adequate amounts of bait to cause greater than 90% mortality, a second study will be conducted to provide more precise data on feed consumption and palatability. The results of this second study will be reported in a separate study report (Springborn Smithers Laboratories Study Number 13760.4109).

Whether written by Springborn Smithers or by RB, this paragraph acknowledges the inadequacy of the Stafford (2002a) study.

In conducting this study and their others discussed in this review, Springborn Smithers almost went overboard in some areas (randomization, analysis of challenge diet and water supply for contaminants) but were negligent in certain basics (obtaining accurate food consumption data, controlling test facility temperature). For all the analysis of the challenge diet, I am not sure how fresh it was when they got it from Purina Mills; and I find no data on particle sizes for the challenge diet.

In their **"Explanation for reports 13760.4102 and 13760.4109: The Efficacy of anticoagulant Dry Bait Rodenticide Using Feed Choice Test with Albino Laboratory Rats (*Rattus norvegicus*, Wistar)"**, RB's Heidi Fuentes and Sean McNear acknowledge "problems with the assessment of food consumption" in the Stafford (2002a) study. Because the 90% Mortality criterion was exceeded in the Stafford (2002a) study "13760.4102", they argue that it "clearly demonstrates efficacy". Claiming acceptance scores of 40.1% and 42.0% in two replicates in study number 13760.4109 (discussed next), Fuentes and McNear claim that the subsequent trial "clearly demonstrates palatability" despite the mortality scores of 85% claimed for both replicates. A 3-day bait-exposure period was used in the 13760.4109 study (see below).

If the rat study by Baroch (2002a) is shown to be applicable to the bait that is to be used in 3282-66 and 3282-74 in the future, neither the Stafford (2002a) study nor the Stafford (2002b) study would be needed to support rat claims for that product. A rat placepack-penetration study still would be needed for 3282-74. As there are no rat claims for 3282-65, no rat study is needed for MOUSE PRUFE II. The "READY MIXED" product 3282-81 historically has consisted of crumbled pellets and, as such, would have to be supported by a separate rat efficacy study.

Stafford, J.M. (2002b) Determining the efficacy of anticoagulant dry bait rodenticide using a feed choice test with albino laboratory rats (Wistar rats, following OPP Protocol guideline 1.203. Unpublished report, Springborn Smithers Laboratory, Snow Camp, NC and Wareham, MA, 124 pp.

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This item is the 13760.4109 study that, according to input from Springborn Smithers and RB, is supposed to show adequate palatability of the test material. Again, Susan Hamel is listed as the "Technical Report Writer" and Jennifer M. Stafford as the "Study Director". The "**INTRODUCTION**" section to this report acknowledges the existence of the Stafford (2002a) study, adding that

> ... interpretation of palatability data was not conclusive ... This study was thus conducted to provide a more accurate assessment of test substance palatability.

The report describes the test material as "4-PA-165, 3/16-inch diameter pellets, Batch No. PP020627", adding that RB indicated that the batch had "a purity of 0.005%" and was stored at room temperature once Springborn Smithers received it. "Page 115" of the Stafford (2002b) report is a "**Reckitt Benckiser** Analytical Services GLP Report" for "Log Number : 020397" and "Formula # 4-PA-165 Batch # B020627". According to this sheet, 3 samples of this batch (one sample from each of 3 "Pail" numbers) assayed at 52-57 ppm (0.0052-0.0057%) Brodifacoum. These results were very-to-fairly close to the nominal concentration of 0.005% Brodifacoum claimed for all 4 products discussed in this review, again suggesting that the previously "proposed" certified limits of 0.004-0.0065% were too broad.

Challenge diet (perhaps from the batch used in the Stafford, 2002a, study) was prepared and analyzed by a Purina Mills facility in Richmond, IN. The challenge diet then was shipped to Springborn Smithers in Snow Camp, NC, where it was frozen at -18°C until it was thawed for use at room temperature or shipped frozen to the Wareham facility for chemical assay.

At Wareham, the 3 "Control" samples (unspiked challenge diet) all were below the LOQ of 0.561 ppm, according to "**APPENDIX II - ANALYTICAL METHODOLOGY**" (pp. 38-48 of the Stafford (2002b) report. That report's "**Table 1.**" (p. 21) shows 2 analyses of challenge diet being below an LOQ of 0.559 ppm.

The report's statement that Springborn Smithers' protocol for this study outlines methods which "meet the requirements specified in" EPA's "Test Guideline (Draft) 1.203" is not completely factual. The period of exposure to toxic bait was limited to 3 days rather than the 15 specified in Protocol 1.203. (The 3-day tests that many registrants have run for second-generation anticoagulants actually were run according to the old – pre-1991 – versions of the acute-bait protocol for Norway rats, 1.209. That protocol was modified in 1991 such that the exposure duration was limited to two days for actual acute rodenticides and to one day for second-generation anticoagulants for which registrants wanted to obtain or retain some sort of "single-feeding" claim. When anticoagulants are tested under the current version of Protocol 1.209, the follow-up period may be extended to 12 days, as Baroch, 2002a did.)

The subjects were 60 Wistar strain albino Norway rats obtained from a single source. For the bioassay, they were caged individually in "Unifab series 1200 welded-angle rack, solid-shelf style

cages stainless steel hanging" with #2 mesh front and bottom" and "presenting a bottom surface area of 815 cm^2", being "22.9 x 35.6 x 20.3 cm" in dimensions (equivalent to 9-X-14-8 inches, which probably were the cage manufacturer's targeted dimensions). The internal surface area was within the requirements indicated in Protocol 1.203.

Diets were offered in 10-oz. glass jars, each being equipped with a

> ... perforated "food follower" that fit inside the jar, on top of the feed, and a "deluxe lid" which slightly reduced the top opening into the jar, and prevented the food follower from being removed.

Rats were fed "LabPro 5002 Certified Rodent Diet" during the acclimation period.

Water might have been provided ("Page 12") at the back of each cage via "an automatic, stainless steel, low pressure water nozzle" which "connected to a common, plumbed-in, pressure regulated water line for continual access". Use of gravity-fed watering systems is "not recommended" in Protocol 1.203 (at pgh. 6.2). That might account for the dual mentions of "pressure". Alternatively, water might have been provided ("Page 14") "at all times via glass water bottles with ball-type watering tubes."

The rats were randomly assigned to one of 3 groups: the control group or either of 2 test groups. Although each group was supposed to consist of 10 males and 10 females, the assignments were so "random" that gender representation was not equal in the 2 test groups. Membership and initial weights of subjects within groups are summarized in the table below.

GROUP	SEX	NUMBER OF RATS	INITIAL BODY WEIGHTS	
			Mean	Range
Control	Males	10	249.1	232.7-265.1
	Females	10	229.8	218.6-243.4
Rep. 1	Males	9	248.1	228.2-260.7
	Females	11	226.3	217.3-239.8
Rep. 2	Males	11	249.4	234.2-262.8
	Females	9	226.5	212.5-238.7

Within groups, differences in mean initial weights between genders were well within the 50-g upper limit indicated in Protocol 1.203.

Results reported for the test groups in the bioassay are summarized in Tables 5a and 5b. In each replicate, 8 males and 9 females died. The 85% mortality results are below the criterion of 90% mortality indicated in Protocol 1.203. All females that perished lost weight (2.8-62.9 g in Rep. I, 2.0-51.8 g in Rep. II) as did all males that perished (22.3-67.6 g in Rep. I, 10.6-44.8 g in Rep. II). Both surviving females gained weight (6.4 g and 11.8) as did 3 of 4 surviving males (18.6-22.3 g). One surviving male lost 7.7 g.

Symptoms of anticoagulant poisoning first were noted after 3 days of the study, essentially at the end of the bait-exposure period. Hemorrhaging was noted in 8 rats, one of which also displayed piloerection. For 7 of these rats, the bleeding was noted at the (ear) "*tag site*", which was a common locus for bleeding in subjects for which the first symptoms were seen on later days. For example, bleeding at the "*tag site*" was the only symptom noted for all 17 rats for which

symptoms (other than death) were reported on Day 4. These animals included 6 of those that were bleeding at the ear tag on the previous day plus 11 more. The other two rats that were bleeding at the ear tag on Day 3 were dead on Day 4. By day 5, there were 5 more deaths and 20 live ones that were bleeding at the ear tag. This information does not prove that ear tagging contributed to the fact or the timing of these animals' deaths, but it seems clear enough that a different method of marking animals should be used in efficacy trials involving anticoagulant baits.

All control-group rats survived the "in-life" portion of the study, and all but one gained weight (4.2-68.3 g for 10 males, 2.8-43.8 g for 9 females). One control-group female lost 0.3 g.

As reported by Stafford (2002b), composite bait acceptance was 40.1% for Rep. I and 42.0% for Rep. II. These data suggest adequate bait acceptance, surpassing the criterion of 33% composite acceptance in Protocol 1.203. (Data for the animal in cage no. 47 were "inadvertently not recorded on day 3" -- 9/20/02. That animal appeared to have strongly favored the bait on Days 1 and 2.) It is clear from Tables 5a and 5b, however, that there were relatively many marginal feeders, assuming that the acceptance data reported reflect actual acceptance. For 11 (28%) of the 40 test-group rats, reported acceptance was less than 15%. These animals included all 6 survivors, none of which reportedly ate more than 3.3 g of bait. That amount of bait should have contained about 0.17 mg of Brodifacoum or between 0.65 and 0.70 mg/kg for rats weighing in the 250-g range. A published acute oral LD_{50} value for Norway rats is 0.27 mg/kg body weight (Timm, 1994, in Prevention and Control of Wildlife Damage, p. G-28), which is why Brodifacoum baits can sometimes pass "one-day" tests like that reported by Baroch (2002a).

The containers of bait and challenge diet that were used for moisture control reportedly ("Page 77") reportedly weighed 328.1 g and 289.6 g, respectively, when loaded on 9/17/02, which coincided with the onset of the bait-exposure period. Of these weights, 40.0 g reportedly were the diets and the remainder the weight of the container (less lid and food follower). Over the course of the bait-exposure period, the weight of the loaded bait container deviated from its initial weight by -0.9 to -1.2 g, while the loaded challenge diet container was 0.2 to 0.3 g below its initial weight. Over the remaining 12 days of the study (excepting Day 12 when the observation was "*inadvertently missed*"), the weight of the loaded challenge diet container was 0 to 0.3 g below its initial weight. For reasons unclear, weight fluctuations of the bait container were monitored over the same period of time, during which they were 1.1 to 1.4 g below the initial weight.

Whether the loaded containers actually were weighed on 9/17/02 is not clear. From "Page 14" of the report, I gather that aliquots of 40.0 g or bait and of challenge diet were weighed out and loaded into plastic bags. These were then dumped into the respective containers for them each day. These containers then were assumed to weigh in at their tare weights plus 40.0 g. At weigh-back, the containers plus food were weighed. That 40.0 g of the diet actually got into the containers assumes that the initial weighings of the diets all were precise and that essentially none of the diets was spilled or left behind in loading or emptying the plastic bags.

The raw data sheets for food consumption list only the weigh-back results. It seems likely that Springborn Smithers entered "tare + 40-g" weights for all of the containers into some spreadsheet where differences were computed once the weigh-back data were entered. Even with tare weights being provided, I cannot evaluate the accuracy of the summarized consumption data efficiently. Consequently, the results shown in Tables 5a and 5b are those that Stafford (2002b) reports. Stafford (2002b) does not report consumption by test day nor does she break it out according to gender as I do in Tables 5a and 5 b.

In light of the substandard mortality results reported, I feel that tedious checking of the accuracy of the reported consumption data would not be a productive use of time. In addition to the problem with taken no weights for loaded containers, such assessments would have to take into account spillage, which is recorded on "SPILL RECORD" sheets that appear on pages 92-112 of

the report. As calculated from pages 92 and 97 and shown in the table below, many times more spilled bait than spilled challenge diet was recovered from test-group cages.

TEST DAY	AMOUNT RECOVERED	
	Toxic Bait	Challenge Diet
1	86.8 g	0.0 g
2	97.0 g	0.0 g
3	97.0 g	1.8 g
ALL	280.8 g	1.8 g

It is not clear to what extent ease-of-recovery affected these numbers (see discussion of this topic in review of Stafford, 2002a). It is noteworthy that relatively little (4.7 g) spilled challenge diet reportedly was recovered for the control group subjects, and all of that was recovered on Day 3. Biased spillage recovery "in favor" of the bait would have had the effect of deflating the acceptance scores for the test groups.

Springborn Smithers probably did a better job with the feed consumption part of this study than they did with the Stafford (2002a) trial, but they should have done weigh-ins for the loaded containers rather than assuming values from their tare weights plus 40.0 g.

According to the Stafford (2002b) report, the temperature in the test room was 21-27°C (about 70-81°C) during the study, ranging about 4 F° beyond the upper limit to the temperature range (20-25°C) stipulated in Protocol 1.204. Relative humidity reportedly was 50-63%, close to the required range (50-55%); while illumination averaged 9 foot-candles.

The mortality criterion was not achieved in the Stafford (2002b) study. Even if the reported data were believed, the acceptance criterion was missed in the Stafford (2002a) study. In their **"Explanation for reports 13760.4102 and 13760.4109: The Efficacy of anticoagulant Dry Bait Rodenticide Using Feed Choice Test with Albino Laboratory Rats (*Rattus norvegicus*, Wistar)"**, RB's Fuentes and McNear suggest that we use the mortality results from the Stafford (2002a) study and the acceptance results from the Stafford (2002b) study and conclude that the data requirement has been met or, in other words, that two wrongs make a right. I am afraid that two wrongs still make two wrongs in this case. Neither study was run well enough to be worthy of much faith in the acceptance results, except to say that the data suggest than more than a few rats did not like the bait and survived exposure to it as a result.

Stafford, J.M. (2002c) The efficacy of anticoagulant dry bait rodenticide using a Place-Pack Penetration Test with albino laboratory rats (*Rattus norvegicus* WISTAR) and 4-PA-165, 3/16-inch diameter pelleted bait. Unpublished report, Springborn Smithers Laboratory, Snow Camp, NC and Wareham, MA, 84 pp.

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Stafford signed off on this one on "*11/14/02*", 3 days after Hamel the "Technical Report Writer" signed off.

The Stafford (2002c) report states that the test substance for this study was

> 4-PA-165, 3/16-inch diameter pellets, 1-ounce place-packs as prepared by the manufacturer and ready to market, Batch No. 811-048B, CAS No. 56073-10-0, reported by the Study Sponsor to have a purity of 0.005% ... received from Reckitt Benckiser North America on 23 April and 25 June 2002.

Thus, it is claimed that material from the same batch was received in two shipments which arrived 63 days apart. Why this happened might be explained by the text quoted below from "Page 10" of the report.

> The initial in-life phase began with the initiation of treatment of 14 June 2002. However, the incorrect size placepacks were inadvertently placed in the test cages. Therefore, the first initiation was terminated on day 1 of the study and all test animals were euthanized. A new batch of test animals was obtained and the in-life phase reported herein was initiated on 26 June 2002 and was terminated on 16 July 2002.

The placepacks for 3282-74 are supposed to hold 1 oz of bait, period. How an "incorrect size" even could have existed is not clear. The bait batch of interest would be the one used for the bait in the placepacks used in the study that went full term. The packs used in the bioassay reportedly held 1 oz of bait, but packs of this size reportedly were received on 4/23/02 as well as on 6/25/02. This account begs the question of the source of the packs of "incorrect size".

Using a different placepack size in the bioassay from the one that is, or is to be, registered would not necessarily negate a placepack penetration study. If the placepacks used were made of the same type and thickness of plastic or other material, the results likely would be applicable to placepacks of different sizes.

The Stafford (2002c) report does not appear to include any information pertaining to assays of the test material for Brodifacoum content.

After it was received, the bait reportedly "was stored at room temperature" (range not indicated).

As with the other Springborn Smithers studies discussed in this review, a Purina Mills facility in Richmond, IN, prepared the challenge diet, analyzed it for certain contaminants, and shipped it to Snow Camp, NC.

Stafford (2002c) states that the challenge diet was "maintained at or below -18 °C from receipt until use" but does not state whether Purina Mills froze it after preparation and/or whether it was or remained frozen during shipment. Purina Mills reportedly found a "representative sample" of the challenge diet to be free of "pesticides, PCBs and toxic metals." Purina Mills reportedly attested to the identity and percentages of the components of the challenge diet but no information is presented on the screening of particle sizes.

In 3 trials each with challenge diet samples spiked to be 4.99, 25.0, or 59.9 ppm, Springborn (Wareham) obtained a mean recovery of 78.4% (SD=5.25%) and a limit of quantitation (LOQ) of 0.561 mg/kg. The 3 "Control" samples (unspiked challenge diet) all were below the LOQ. These figures come from **"APPENDIX II - ANALYTICAL METHODOLOGY"** (pp. 40-49 of the Stafford (2002c) report. The main report's "Table 1." (p. 20) states that 2 analyses of challenge diet showed Brodifacoum to be absent from the challenge diet (or at least being below an LOQ of 0.559 ppm).

The bioassay reportedly was run in the Springborn Smithers facility in Snow Camp, NC.

The report states that the bioassay was run according to Springborn Smithers rendition ("Protocol No.: 040202/FIFRA/Rat Eff Placepack") of OPP Protocol 1.217, 1992 version. On 6/3/02, before the trial run to completion was begun, Springborn Smithers amended their own version of Protocol 1.217 by deleting the passages indicated below.

> At least 40 g of challenge diet will be available per animal per day. The food offered in each container will be equal and consistent throughout the test.
>
> ... and the amount of Challenge Diet consumed during the test and post-test periods will be recorded.

These passages came from "**Section 2.5.3**" and "**Section 2.5.6**", respectively, of the Springborn Smithers protocol. In removing this text (which is consistent with OPP Protocol 1.203), Springborn Smithers offered the following "**justification:**"

> Food consumption is not a required parameter to be recorded for this study. Therefore, feeders will be kept at a level that ensures adequate challenge diet for all animals at all times and will exceed the 40 g minimum, but will not be measured. Rather, feeders will be monitored such that food is kept above a predetermined level in the feeders, and which exceeds 40 g per animal.
>
> This amendment does not result in negative impact on the quality or integrity of the study.

Protocol 1.217 does not specifically state that challenge diet consumption should be monitored nor does it specify the amount of challenge diet to provide beyond stating that there should be two or more feeders containing challenge diet per cage when subjects are group-caged. Failure to specify the minimum amount of challenge diet to provide and failure to clearly state that the total amount of challenge diet provided per cage must equal or exceed the total amount of bait offered in placepacks in the same cage are shortcomings of Protocol 1.217 which will be addressed upon its imminent revision. (Protocol 1.218, the mouse placepack test for anticoagulants, is not as deficient as Protocol 1.217 in these areas.) I can see both sides of the issue with respect to monitoring the amount of challenge diet consumed. In a placepack-penetration study, obtaining more than a rough acceptance figure is difficult because the amount of bait taken can only be grossly estimated. Data on consumption of challenge diet could be used, however, to assess the general health and appetites of control-group subjects as well as those of test-group rodents that survive the bait exposure period.

Wistar strain Norway rats were used as subjects in this study. The animals were communally caged in single-sex subgroups of 5/cage in "galvanized oval stock tanks" which "measured 2.4 m x 0.91 m x 0.61 m". Assuming the first two dimensions to be length and width, these tanks were almost 8 ft long and nearly a yard wide. Figuring rounded corners and tapered sides, the floor area of each tank probably was in the neighborhood of 20 ft^2, which is within the limitations set in paragraph 4.1 of Protocol 1.217.

Water reportedly was supplied via "8 ounce glass jars" equipped with "steel tubes fitted with a ball-point tip". The tubes were all of the waterers that "protruded into the cage".

Challenge diet was provided in two "10-ounce glass jars" of the type described in the Stafford (2002a) report. It is not clear whether the jars were secured in any way that would have prevented rats from tipping them over, but they were "spaced evenly within each cage (control and treatment)." These "10-ounce jars" reportedly

contained 300g of feed when full, but were marked with a line at the 200 g point. OPP Diet was monitored such that the level stayed above the 200 g mark, ensuring a minimum of 40 g per animal per day per feeder (40 g x 5 animals = 200 g). The resulting amount of OPP Diet provided (a minimum of 400 g per cage) closely approximates the amount of bait provided (15 packs of 28 g or 420 g per cage).

That arrangement probably provided a reasonable balance in the amount of the two diets available. (The amount of bait in 15 1-oz packs would be more like 425 g.) That the placepacks could be removed to places of relative safety would have afforded them some advantage, but the same sort of advantage would obtain in actual baiting situations.

A total of 12 of the tank cages were used to house the 3 groups of 20 rats each (4 subgroups/group) used in this study. There were 2 test groups of 10 males and 10 females each and 1 similarly comprised control group. Starting weights reported for the rats used in this study are summarized below.

GROUP	SEX	INITIAL BODY WEIGHTS	
		Mean	Range
Control	Males	243.2	233.3-253.1
	Females	219.8	204.2-232.4
Rep. 1	Males	244.2	227.1-257.9
	Females	222.9	213.3-238.2
Rep. 2	Males	242.6	224.3-263.1
	Females	221.9	207.2-235.2

These data fall within the animal weight requirements of Protocol 1.217.

Rats were to be exposed to the choice between bait from the placepacks and challenge diet from the jars for 15 consecutive days, after which no new placepacks were to be added and challenge diet only was offered to surviving animals.

Stafford (2002c) reports that all test-group rats died during the bait-exposure period (100% mortality). In Replicate 1, males died 4-12 days after the onset of bait exposure, while females died in 5-12 days. In Replicate 2, times to death were 5-9 days for both the males and the females. Among the males in Replicate 1 there were 5 that lost weight (3.8-59.0 g) and 5 that gained (8.9-21.5 g). Among the females in Replicate 1 there were 9 that lost weight (6.1-64.9 g) and 1 that gained (6.8 g). In Replicate 2, 7 males lost weight (2.1-43.0 g) and 3 gained (0.8-25.6 g). Replicate 2's females included 9 that lost weight (1.2-62.2 g) and 1 that gained (10.7 g).

Control-group animals reportedly all survived and gained weight (36.5-75.4 g for the males, 5.4-41.7 g for the females).

Reported use of placepacks in the 8 test-group tanks is summarized below.

	REPLICATE 1					REPLICATE 2				
	Cage #					Cage #				
	2	9	11	12	Total	3	4	5	7	Total
PACKS										
Placed	15	15	15	15	60	15	15	15	15	60
Added	11	18	24	6	59	30	20	26	11	87
Total Used	26	33	39	21	119	45	35	41	26	147
# Penetrated	23	30	36	19	108	44	35	41	27?	147?
% Penetrated	88%	91%	92%	90%	91%	98%	100%	100%	104%	100%?

It seems clear enough that the test-group rats went for the bait in the placepacks and that the material of which the packs were made was not a significant deterrent to them.

According to the Stafford (2002c) report, the temperature in the test room was 21-29°C (about 70-84°C) during the study, going about 7F° beyond the range (20-25°C) stipulated in Protocol 1.217. Relative humidity reportedly was 50-60%, close to the required range (50-55%); while illumination averaged 81.5 foot-candles.

There were some problems with the conduct of this study. For the limited purpose of showing that some type of Norway rat will penetrate the placepack and consume enough bait to produce an incidence of mortality $\geq$90%, the Stafford (2002c) study is adequate. Its results are applicable to the placepack material used in the study and to the bait used in the study. These results may be "bridged" to different bait formulations so long as the placepack material is not changed and the new bait formulations perform to criteria in at least one laboratory efficacy study run according to Protocol 1.203, 1.209, and/or 1.213.

House Mice

Stafford, J.M. (2002d) 4-PA-165, 3/32-inch diameter pellets: The efficacy of anticoagulant dry bait rodenticide using a feed choice test with albino laboratory mice (*Mus musculus*, CD-1). Unpublished report, Springborn Smithers Laboratory, Snow Camp, NC and Wareham, MA, 128 pp.

MRID# 458121-09

This was another Springborn Smithers trial for which the challenge diet was formulated by Purina Mills in Indiana and the bioassay and chemical assay were conducted by Springborn Smithers in North Carolina and Massachusetts, respectively. Again, there is no account of the handing of the challenge diet until Springborn Smithers received it at Snow Camp, NC. For reasons unexplained, Springborn Smithers elected to use CD-1 strain laboratory house mice rather than the Swiss Webster strain that is recommended by Protocol 1.204. Although the report is attributed solely to Stafford on its title page, Susan M. Hamel is identified on "Page 5" as the "Technical Report Writer".

The test material is identified in the report as "4-PA-165, 3/32-inch diameter" and as "D-Con® Mouse Prufe II". It reportedly had a "Purity" of "0.005% (50 ppm)", which clearly is a reference to its nominal concentration of Brodifacoum. Springborn Smithers stored this bait at room temperature.

At the end of the report's "**APPENDIX II - ANALYTICAL METHODOLOGY**" is a single sheet of paper entitled "**Reckitt Benckiser Analytical Services GLP Report**" which implies that 2 assays each of 3 samples of "Formula # 4-PA-165 Batch # B02029A Reference #811-048A (D-Con Mouse Prufe II 3/32)" came in at 48-50 ppm (0.0048-0.0050%) Brodifacoum. The assay was run some time between "02/04/2002" and "02/13/2002".

The challenge diet that Purina Mills prepared was found to be negative for Brodifacoum with a limit of detection of 0.0000561% (indicated in "**APPENDIX II**" ("Page 48")and 0.0000599% on Page 24 of the basic report. Once they received it from Purina Mills, Springborn Smithers stored the challenge diet at -18°C until brining it to room temperature for use in the bioassay.

The CD-1 strain mice were obtained from a commercial source a week before the start of the bait-exposure phase of the bioassay. The animals were house individually (an option permitted by Protocol 1.204). Stafford (2002d) describes the cages used as follows:

> ... Unifab series 1200 welded-angle rack, solid-shelf style cages, with series 470 open-top, hanging cage bins. A solid stainless steel sheet of metal was inserted into each cage, which covered the floor of the cage to provide a solid bottom. Each cage measured 22.9 x 35.6 x 20.3 cm, presenting a bottom surface area of 651.7 cm^2. Each bin was composed of stainless steel, #2 mesh front and bottom (which was covered by the insert), with solid stainless steel sides and back. Laboratory grade pine shavings were added to a depth of approximately 2.5 cm, covering the metal bottom of each cage.

In paragraph 3.1, Protocol 1.204 (revision of 6-18-91) states,

> Mice should be placed in solid-bottom all-metal cages designed to hold laboratory mice or in specially constructed or modified cages suitable for maintaining house mice for this type of test.

Due to problems created when wood shavings were added to the cages (see below), it might have been better if the mice had been housed on wire-bottom cages.

Some 60 mice were used. These were assorted into 3 groups of 20 mice each (10 males and 10 females). The two test groups were offered a choice between bait and challenge diet for 15 days (or until death) followed by a 5-day follow-up period during which they were offered only challenge diet. The control-group mice were offered only challenge diet (and water) for 20 consecutive days. Diets were offered to the mice in 20-g amounts in

> 4-ounce feeders, [which] when filled with 20 g of Challenge Diet or bait, allowed space for mice to climb into the feeders and wallow in the feed. To reduce this space, the lower half of the feeding jars were filled with coarse sand, on top of which was placed an aluminum foil disk to separate the sand from the feed. At this point the tare weight of each feeder was recorded and then the challenge diet or the rodenticide bait was added. Two feeders, each containing at least 15 g of Challenge Diet were placed at the front of each control cage. Two feed jars were similarly placed in each treatment cage, but the anticoagulant bait was placed in one and Challenge Diet in the other. Each treatment cage feeder was supplied with at least 15 g of the appropriate feed type. All feeders were weighed daily to determine the amount of feed removed, and additional feed was added to bring the total feed jar weight back to within 0.1 g of the initial weight. The positions of the feeders were

reversed daily in all cages. Food consumption values were calculated at the end of the in-life phase of the study. All feed measurements were to the nearest 0.1 g.

Whether the foil would exclude urine from passing into the sand below (thereby compromising weigh-back data) or hold up against mouse incisors is not clear. Any sand that worked its way up through the foil might have adversely impacted consumption of the diet associated with the leakage. As it consists largely of finely materials, the challenge diet might have been more strongly affected in this regard than the pelleted bait. Why the facility did not simply use smaller containers is not clear to me.

Bait pellets reportedly averaged 0.04 g (range 0.018-0.062 g, n=20) with groups of 5 pellets averaging 0.22 g (range 0.187-0.246 g, n=10)

Starting weights reported by Stafford (2002d) for the mice used in this study are summarized below.

GROUP	SEX	INITIAL BODY WEIGHTS	
		Mean	Range
Control	Males	27.2	25.5-29.4
	Females	22.2	19.6-24.9
Rep. 1	Males	27.7	25.2-31.0
	Females	21.1	19.0-23.2
Rep. 2	Males	26.6	23.7-31.1
	Females	22.1	20.3-26.0

Across groups, the maximum allowed between-sex difference in average weight (5 g) essentially was realized, although the gap was somewhat too wide for Rep. 1. To get the weights as close as they did, Springborn Smithers used males that were 6 weeks old and females that were 7 weeks old. This time, they divided the animals by sex before going into their randomization process.

Stafford (2002d) reports that all but one mouse died in the Rep. 1 test group (95% mortality), that all mice died in the Rep. 2 test group (100%), and that no mice died in the control group (0%). The survivor in Rep. 1 was a female. Deaths occurred from days 5 to 18 in Rep. 1 and from days 4 to 11 in Rep. 2. Initial symptoms of toxicosis were detected 3 days into the bait-exposure phase of the trial. The most common early symptoms included bleeding at the ear-tag site and "*moving very slowly, not escaping capture*". Later signs included piloerection, body shaking, swollen bodies, lethargy, and lying on the animal's side. Symptoms were not reported for the female survivor in Rep. 1.

In Rep. 1, all males weighed less (1.1-6.3 g) at death than they did prior to the onset of bait exposure. Of the 9 Rep. 1 female victims, 8 lost weight (2.6-6.5 g). The female survivor gained 1.9 g. In Rep. 2, all 10 males lost weight (3.5-8.3 g) as did all females (3.0-6.0 g). All 10 control-group males gained (0.5-4.9 g) as did 9 control-group females (0.3-4.6 g). One control-group female lost 0.8 g.

Stafford (2002d) reports composite bait acceptance figures of 32.0% for Rep. 1 and 30.8% for Rep. 2 but expresses no confidence in these data because,

More than 50% of the individual daily food consumption values indicate that individual mice consumed more than 20% of their body weight. Physiological limitations on daily mouse consumption flag these values as incorrect. The high feed consumption values are believed to be the result of a failure (on the part of the performing laboratory) to detect OPP challenge diet that was buried ("cached") by individual mice in the wood chips used as cage bedding. This resulted in insufficient accounting for "spilled" feed, which in turn resulted in an over-estimate of the consumption of the OPP challenge diet. Very little bait was spilled, but when spilled or cached, it was easily observed because of its green color. The OPP challenge diet on the other hand was similar in color to the wood chips, and was difficult to find among the chips. Mice chewed wood chips into a substantial quantity of fine "sawdust-like" dust which resembled the challenge diet in texture. This problem resulted in a conservative estimate of what percent of the overall diet consisted of bait. To resolve this problem and to facilitate the assessment of palatability of the test substance, an additional feeding test will be conducted...

As the author herself has no confidence in the consumption data, there would seem to be little point to presenting or discussing them in detail. I am not sure that her 20%-of-body-weight flagging was appropriate. For a 25-g mouse, combined consumption above 5-g would have been flagged. Such figures are not uncommonly reported for mice, especially when the diets involved are relatively high in sucrose and/or another sweetener and are not designed to be nutritionally balanced and the species involved has a high metabolic rate and a high surface-to-volume ratio.

According to the Stafford (2002d) report, the temperature in the test room was 19-28°C (about 66-82°C) during the study, going about -2 and +5 F° beyond the temperature range (20-25°C) stipulated in Protocol 1.204. Relative humidity reportedly was 50-60%, close to the required range (50-55%); while illumination averaged 47 foot-candles. It is odd that the test facility did a better job of controlling relative humidity than of controlling temperature.

The mortality figures reported for both replicates exceed the 90% mortality criterion in Protocol 1.204. The reported bait acceptance figures were slightly below the criterion of 33%, but the author of the report expresses no confidence in those data. I have less confidence than the author that the figures reported underestimate actual acceptance. How else might one explain animals surviving into and past the follow-up period after having been exposed to a bait that is 0.005% Brodifacoum?

In addition to the problem with the acceptance data, this study suffers from many of the problems mentioned for the Springborn Smithers rat studies discussed above plus the business with sand and foil in the feed cups. Due to these various problems, the study will not be accepted. Stafford's experiences do suggest that it might be wise to require screen-bottom cages in Protocol 1.204 when the mice are individually caged.

Stafford, J.M. (2002e) Determining the efficacy of anticoagulant dry bait rodenticide using a feed choice test with the house mouse, following OPP protocol guideline 1.204. Unpublished report, Springborn Smithers Laboratory, Snow Camp, NC and Wareham, MA, 125 pp.

MRID# 458121-08

This report is of the second choice feeding study with house mice that was promised in the Stafford (2002d) report. The bait-exposure phase of this bioassay was shortened from 15 days to 3 days; and the post-exposure monitoring period was extended to 12 days.

For this trial, the challenge diet again was formulated by Purina Mills in Indiana and the bioassay and chemical assay were conducted by Springborn Smithers in North Carolina and Massachusetts, respectively. There is no account of the handing of the challenge diet until Springborn Smithers received it at Snow Camp, NC. Springborn Smithers again elected to use

CD-1 strain laboratory house mice rather than the Swiss Webster strain that is recommended by Protocol 1.204. Although the report is attributed solely to Stafford on its title page, Susan M. Hamel is identified on "Page 5" as the "Technical Report Writer".

The test material is identified in the report as "4-PA-165, 3/32-inch diameter pellets, Batch # B02029A Reference #811-048A, CAS No. 56073-10-0". Therefore, the same batch of bait was used in this study as in the Stafford (2002d) trial. The same "**Reckitt Benckiser Analytical Services GLP Report**" that appeared in the report of the Stafford (2002d) trial appears in this one, but it appears in the "**APPENDIX III - RAW DATA, DOCUMENTATION AND SPONSOR CORRESPONDENCE**" section (on Page 123) rather than in the "**APPENDIX II - ANALYTICAL METHODOLOGY**" section. That sheet implies that 2 assays each of 3 samples of "Formula # 4-PA-165 Batch # B02029A Reference #811-048A (D-Con Mouse Prufe II 3/32)" came in at 48-50 ppm (0.0048-0.0050%) Brodifacoum. The assay was run some time between "02/04/2002" and "02/13/2002", more than 7 months before the start of this bioassay.

The challenge diet that Purina Mills prepared was found to be negative for Brodifacoum with a limit of detection of 0.0000561% (indicated in "**APPENDIX II**" ("Page 45")and 0.0000599% on Page 22 of the basic report. Once they received it from Purina Mills, Springborn Smithers stored the challenge diet at -18°C until brining it to room temperature for use in the bioassay.

The CD-1 strain mice were obtained from a commercial source a week before the start of the bait-exposure phase of the bioassay. The animals were housed individually (an option permitted by Protocol 1.204) in a manner like that described for the Stafford (2002d) study (i.e., wire cage bottoms were covered with a "solid, stainless steel sheet of metal". Pine shavings were used on the cage floors "during acclimation". Due to the problems with recovery of spillage mentioned in the Stafford (2002d) report, the shavings were removed for the bait-exposure period and replaced with "sheets of white cloth, measuring approximately 30.5 x 25.4 cm" which also "served to provide bedding, cover, and absorbent material within the cage."

Diets were provided in

> Unifab, 2 ounce glass jars with perforated 'food follower" [sic] that fit inside the jar, on top of the feed, and a "deluxe lid" which slightly reduced the top opening into the jar, and prevented the food follower from being removed. The design is intended to prevent soiling of and nesting in feeder contents.

The improvements here are the switch to a more mouse-appropriate container size and the resultant lack of perceived need to put sand and foil below the diets. For the bioassay proper, Springborn Smithers weighed out 15-g amounts of and put them in little plastic bags for initial loading into pre-weighed container, lid, and food-follower arrangements. Thus, there apparently was not actual weigh-in of loaded containers. There were weight-outs, and the difference between these and the computed weigh-ins were concluded to represent daily consumption figures, with adjustments having been made for occasional recoveries of spillage. Spillage was labeled by cage and diet, dried overnight at approximately 37.8°C as necessary" (37.8°C being equivalent to 100°F), and used to adjust daily consumption figures. Most of the recovered spillage from test-group cages during the bait-exposure phase was bait.

Water was supplied via glass 8-oz bottles equipped with ball-point tip stainless-steel sipper tubes.

Starting weights reported by Stafford (2002e) for the mice used in this study are summarized below. Note that the facility's randomization process got screwed up to the point where there were unequal numbers of males and females in both test groups. The timing of this study should have been too late in the learning process for a gaffe like that to occur.

GROUP	SEX (n)	INITIAL BODY WEIGHTS	
		Mean	Range
Control	Males (10)	26.7	24.1-29.1
	Females (10	22.2	19.1-25.5
Rep. 1	Males (11)	27.3	23.4-29.7
	Females (9)	22.6	20.1-26.0
Rep. 2	Males (9)	26.1	22.0-28.7
	Females (11)	22.7	18.8-27.5

Although the numbers of males and females were off, the differences between sexes in mean body weight were under the 5-g maximum in all groups.

Tables 6a. and 6b. summarize the results obtained in the test groups. Mortality in Rep. 1 was just 65% with 3 of 11 males and 4 of 9 females surviving. In Rep 2, Mortality was 60%, with 4 of 9 males and 4 of 11 females surviving. These results were well below the Mortality criterion of 90% in Protocol 1.204. Even if the conduct of this study had been flawless, these poor results would have flunked it.

In general, test-group survivors in this trial gained weight, while victims lost. Survivors gaining weight included all 3 male survivors (0.1-4.1 g) and 2 of 4 female survivors (2.2-4.7 g) in Rep. 1, with the other 2 female survivors losing 0.1 and 0.4 g. The 8 male victims in Rep. 1 all lost weight (0.8-6.7 g) as did all 5 female victims (0.7-8.7 g). Three of 4 male survivors gained weight (0.7-0.9 g) in Rep. 2 as did all 4 female survivors (0.5-1.2 g). All 5 male victims in Rep. 2 lost weight (2.2-6.6 g) as did 6 of the 7 female victims (4.1-8.0 g). One female victim gained 0.6 g.

All mice in the control group survived. All but 1 of these mice gained weight over the course of the study. One male lost 1.6 g, while the other 9 gained (0.6-2.6 g). Females gained 0.6-4.3 g.

Stafford (2002e) reports food consumption results in extremely convoluted manner, not even summarizing the data by group or gender. The raw data are no help in this regard either because initial loaded weights for food containers are not supplied, except in the case of the two containers that were used for purposes of moisture control. Spillage data are presented by animal and diet by day, but I have no numbers to which to apply those adjustments. As the study is a flunker anyway due to the poor mortality results, the data that I present in Tables 6a. and 6b. were taken directly from Stafford's (2002e) "**Table 4.**" Those numbers indicate a couple of negative consumption figures (a biological impossibility for rodents) for challenge diet (hence individual Acceptance scores exceeding 100%).

Overall, composite acceptance scores for groups and sex classes within groups were in the 40-60% range, with mean scores being similar. Such results mask a bipolar distribution in which 15 mice accepted the bait at 22% or less and survived, with 13 of those accepting it at less than 10%, and 25 mice accepted bait at 25.3% or higher and died, with 21 of these accepting bait at more than 70% of total food intake. If these results reflect the animals' actual preferences rather than some experimental artifact, they would mean that a substantial fraction (⅔) of the CD-1 house mice exposed to the bait did not like it to the point where they survived exposure to it.

Stafford and/or Hamel composed a "**CONCLUSIONS**" paragraph which reads as shown below.

> Control animals demonstrated no abnormal behavior and experienced no mortality, indicating that mortality and symptoms of toxicity observed in the treatment replicates was the result of dietary exposure to the test substance. During the study, test animals in treatment replicates 1 and 2 experienced 65% and 60% mortality, respectively. Bait consumption during the 3 days of exposure was 53.0% and 54.9% respectively, of total food consumption in replicates 1and 2 thus demonstrating that the test substance had adequate palatability based on U.S. Environmental Protection Authority OPP Protocol 1.204..

Such spin notwithstanding, this study fails due primarily to the low mortality scores reported.

According to the Stafford (2002e) report, the temperature in the test room was 21-27°C (about 70-81°C) during the study, ranging about 4 F° beyond the upper limit to the temperature range (20-25°C) stipulated in Protocol 1.204. Relative humidity reportedly was 50-63%, close to the required range (50-55%); while illumination averaged 9 foot-candles.

In their document entitled **"Explanation for reports 13760.4101 and 13760.4108: The Efficacy of Anticoagulant Dry Bait Rodenticide Using Feed Choice Test with Albino Laboratory Mice (*Mus musculus, CD1*)"**, Fuentes and McNear attempt to persuade EPA that the Stafford (2002d) study really should be accepted despite the author's lack of confidence in the acceptance data due to the alleged certainty that challenge diet intake was "overestimated by, on average, 2-3 times". Using assumptions most favorable to them, they go on to suggest that the amounts of challenge diet reportedly consumed were "up to 5-6 time [sic] more than expected. Such arguments are not persuasive. For all any of us knows at this point, mice ate sand along with challenge diet and that potentiated the efficacy of the amounts of anticoagulant that they consumed. The study was run poorly and having to repeat it is the price of an education. Consulting with EPA along the way might have helped Springborn Smithers immensely.

In the same note, Fuentes and McNear mention the "high palatability" of the test material used in the Stafford (2002e) study, noting also the poor mortality results but not characterizing them as such. *In anticoagulant trials, high palatability and low mortality usually betrays a grossly* underformulated bait. If the assay result reported for the test material used in the Stafford (2002e) study reflected its composition during the bioassay, underformulation would not have been a problem in that study. Instead, there seemed to me a behavioral problem: 15 of 40 test-group mice (⅜ of them) rejected the bait and were not killed by it. I see no good news there.

Stafford, J.M. (2002f) The efficacy of anticoagulant dry bait rodenticide using a Place-Pack Penetration Test with albino laboratory mice (*Mus musculus, CD-1*) and 4-PA-165, 3/16-inch diameter pelleted bait. Unpublished report, Springborn Smithers Laboratory, Snow Camp, NC and Wareham, MA, 114 pp.

MRID# 458121-13

This report covers the second of two bioassay rounds. In the second paragraph of the report's Introduction, Stafford (or Hamel) states the following:

> The study was initiated on 9 May 2002, the day the Study Director signed the protocol, and was completed on the day the Study Director signed the final report. The initial in-life phase began with the initiation of treatment on 13 June 2002. By day 9, control mortality exceeded the limit set by U.S. EPA guideline. Prior to dying, two of the three control mice displayed symptoms similar to those of mice that had been exposed to the test bait. Due to the possibility that bait may have been inadvertently spilled into control cages, the first initiation was terminated on day 11 of the study and all animals were euthanized. A new batch of test animals was

obtained and the in-life phase reported herein was initiated on 20 August 2002 and was terminated on 9 September 2002.

In other words, 3 control-group mice died within 9 days of the onset of the bait-exposure period and 2 of them appeared to be suffering from anticoagulant poisoning. Springborn Smithers then ended the test and killed the survivors. Had the lab continued the trial, more control-group mice might have died. The caging arrangement used may have facilitated the assumed cross contamination of feed, and is it not clear whether of what steps were taken in the second run to keep cross-contamination from happening again.

Stafford (or Hamel) describes the test material as

> 4-PA-165, 3/16 inch diameter pellets, 1-ounce placepacks as prepared by the manufacturer and ready to market, Batch No. 811-048B, CAS No. 56073-10-0, reported by the Study Sponsor to have a purity of 0.005%...

The "**Reckitt Benckiser** Analytical Services GLP Report" appended to this efficacy document indicates that "Log Number : 020098" of "Formula # : 4-PA-165" assayed at 0.0050-0.0052% Brodifacoum in 2 runs each of 3 samples.

Once they got it, Springborn Smithers stored the placepack product "at room temperature in the original container in a dark cabinet."

Again, the challenge diet reportedly was prepared by Purina Mills, shipped to the Snow Camp, NC, facility for use in the bioassay. From there, some was sent on to Wareham, MA, for chemical analysis. Once Springborn Smithers got hold or it, the challenge diet reportedly was frozen at -18°C until it was used (at "room temperature" for the bioassay).

Springborn Smithers reportedly found the challenge diet to be free of Brodifacoum (i.e., below limits of quantitation of 0.599 ppm according to the text of the report and 0.561 ppm according to "**Table 1A.**" of "**APPENDIX II - ANALYTICAL METHODOLOGY**").

Springborn Smithers used CD-1 laboratory mice rather than Swiss Webster strain. Mice were group-caged in single-sex subgroups of 5 animals each. Test groups were comprised of 4 such subgroups, 2 of males and 2 of females. A control group was similarly comprised. Starting weights reported for the mice used in this study are summarized below.

GROUP	SEX	INITIAL BODY WEIGHTS	
		Mean	Range
Control	Males	24.0	21.7-25.8
	Females	23.1	19.5-26.0
Rep. 1	Males	25.8	21.2-27.3
	Females	23.2	20.2-26.0
Rep. 2	Males	23.9	20.5-26.3
	Females	23.7	22.3-25.4

These weights and the differences in mean weights between the sexes in the various groups are within the requirements of Protocol 1.218. For all of the report's discussion about randomization procedures, it still happened that 7 of the males in Rep. 1 were heavier than any of the males in the control group at the start of the study.

According to the report,

> Mice were group housed in polycarbonate tubs divided in half by stainless steel flashing, to create two cages from each tub. The tubs were covered by lids made of 2.5- x 1.3-cm (1 x ½ in) wooden frames overlaid with 0.16-cm (1/16 in.) metal screen. Each cage [presumably half a tub] measured 50.8 cm (20 in.) high and offered a bottom surface area on 812.9 cm^2. Laboratory grade pine shavings were added to a depth of approximately 2.5 cm, covering the bottom of each cage.

This arrangement suggests how the aforementioned cross-contamination might have occurred, namely that test- and control-group animals might have been on opposite sides of one divided tub.

Regarding caging, Protocol 1.218 states:

> Mice should be placed in solid-bottomed all-metal cages designed to hold laboratory mice or in specially constructed or modified cages suitable for maintaining house mice for this type of study. If mice are house singly, each cage must have a bottom surface area of at least 500 cm^2 (0.538 ft^2). If mice are group-caged, each enclosure must have a bottom surface area of at least 2,000 cm^2.

In as much as the surface area reportedly offered to the group-caged mice was less than half of the specified minimum and the potential for cross contamination existed and apparently was realized in the first attempt at completing this study, the decision to divide the tubs was wrong two ways.

At least one 7-oz glass jar equipped "with a perforated 'food follower'" plus "a 'deluxe lid'" was used as the container for challenge diet. One or more "8-ounce glass jars" equipped with "screw-on, stainless steel tubes fitted with a ball-point tip" provided water.

After an acclimation period during which mice in all groups were offered "LabPro 5002 Certified Rodent Diet", the bioassay proper began. Control and test subgroups were offered OPP rat and mouse challenge diet apparently in 2 single jars

> and feed was monitored such that the total amount available each day always exceeded 15 g per animal. Each jar contained 100 g of feed when full, but were [sic] marked with a line at the 75 g point. OPP Diet was monitored such that the level stayed above the 75 g mark, ensuring a minimum of 15 g per animal per day per feeder (15 g x 5 animals = 75 g). The resulting amount of OPP Diet provided (a minimum of 150 g per cage) closely approximates the amount of bait provided (5 packs of 28 g or 140 g per cage). The close approximation of each deed [sic] type provided allowed unrestricted feeding on the Challenge Diet.

Indeed, it would appear that enough challenge diet was available so as not to force animals to consider the contents of the placepacks as food.

As suggested above, each test group also received 5 placepacks initially, with packs being replaced after their "contents were largely consumed, spilled or fouled."

Each day that an animal died in a treatment cage, one place-pack was removed from that cage along with the fatality. To calculate daily values for new penetrations, the number of fatalities and corresponding removed place-packs were taken into account...

The "choice" phase of the test was continued for 15 days, after which time, surviving test-group mice were offered only challenge diet for 5 more days or until the mice died. Control-group mice got only challenge diet as food for 20 straight days.

Reported use of placepacks in the 8 test-group half-tub cages is summarized below.

	REPLICATE 1					REPLICATE 2				
	Cage #					Cage #				
	3	4	11	12	Total	1	2	7	8	Total
PACKS										
Placed	5	5	5	5	20	5	5	5	5	20
Added	12	16	12	4	44	10	18	8	20	56
Total Used	17	21	17	9	64	15	23	13	25	76
# Penetrated	14	20	14	9	57	15	19	10	25	69
% Penetrated	82%	95%	82%	100%	89%	100%	83%	77%	100%	91%

These data suggest that mice had little inhibition against or difficulty in penetrating placepacks.

As a likely result of ingesting bait, all test-group mice died. In Replicate I, males died 4-9 days after the onset of exposure to placepacks, while females died in 4-13 days. In Replicate II, males died in 4-10 days and females in 5-19 days, with 2 females living beyond the 15-day bait-exposure period. The 100% Mortality score eventually achieved in both the groups exceeds the 90% Mortality criterion for Protocol 1.218. No deaths were reported in the control group during the second attempt at completing this bioassay.

Eighteen of 20 mice in Replicate I weighed less at death than they did initially (a day before the start of the acclimation period. All females in this group lost weight (2.0-5.9 g) while 8 males also lost (0.1-3.6 g) and 2 gained (0.5 and 0.8 g). In Replicate II, 17 of 20 mice lost weight, including all females (0.9-10.3 g) and 7 males (0.3-3.1 g). Three males gained (0.3-1.9 g). Nine of 10 control-group males gained weight (3.3-8.7 g), while one lost 4.7 g. Nine of 10 control-group females gained weight (1.1-3.5 g), while one maintained a weight of 25.6 g.

According to the Stafford (2002f) report, the temperature in the test room was 21-27°C (about 70-81°C) during the study, going about 4F° beyond the range (20-25°C) stipulated in Protocol 1.218. Relative humidity reportedly was 50-63%, close to the required range (50-55%); while illumination averaged 40 foot-candles.

The biggest problem with this study is the design of the cages which (1) were way too small and (2) may have allowed cross contamination of material, even in the study in which none of the control-group subjects died.

The exact composition of the test material is not established by the information provided in Stafford's (2002f) report. The identity of the placepack material also is not established.

Baroch, J. (2002b) House mouse (*Mus musculus*) Acute Dry Bait Using Mouse Prufe II with Brodifacoum (0.005 %): one-day test. Unpublished report, Genesis Laboratories, Inc., Wellington, CO, 98 pp.

MRID# 458121-11

Baroch (2002b) reports that this trial was conducted according to Protocol 1.210, with the bait-exposure period being limited to one 24-hr period as is required when the test is intended to support "single night's feeding" claims for second-generation anticoagulants.

Baroch describes the test material as

> blue-green colored pellets, about 3/32 inches in diameter and an average of 5/16 inches in length.

The test material reportedly had a "Formula number" of "4PA-165" and a "Notebook Reference Number" of "738-015". Genesis assigned the inventory number "00-TS-34" to the 8900 g of the test material that it received.

"Appendix C1" (pp. 55-59 in the Baroch, 2002b, report) consists of a report describing analyses of "Mouse Prufe II Bait (Formulation No. 4PA-165, NB Reference No. 738-015, Genesis TS No. 00-TS-34)" and a sample of OPP challenge diet for Brodifacoum content. Reported results were a mean concentration of 0.00451% (±0.00005%) for 3 samples the toxic bait and "Not Detected" for the challenge diet. The individual samples (3 runs each) of toxic bait tested out at 0.00455% (±0.00006%), 0.00453% (±0.00001%), and 0.00447% (±0.00003%) Brodifacoum. These results round to the bottom of the 0.0045-0.0046% a.i. This same report indicates limits of detection and quantitation of 0.000053% and 0.000188%, respectively. As it mentions "difethialone" where the reader expects to see "brodifacoum", it seems that the analytical report was prepared by editing an earlier report for that other compound.

In Appendix D9", Baroch (2002b) provides raw data on "**CHALLENGE DIET (CD) PREPARATION WEIGHTS**". The information there includes the amounts of ground-grain components that passed through various screen meshes. In the report itself, Baroch (2002b). For the ground corn, Genesis seemed to be shooting at targets of 30% of material being retained by a #10 screen, 50% retained by a #20 screen, and 10% passing through a #20 screen. As indicated in Protocol 1.210, 75% (±5%) of the whole yellow ground corn (not degerminated) used in OPP rat and mouse challenge diet is supposed to pass through a #10 screen and 50% is to be retained by a #20 screen. Genesis hits the second figure dead on but just barely falls within the limits allowed for the first. This means that their challenge diets are on the coarse side of the acceptable range. The oat screening figures were right on for the diets prepared for mouse trials and consistently a bit off for the rat studies. (On 1/26/04,I spoke with Richard Poche, Director of Genesis Laboratories, about this situation. He indicated tor me that we had discussed the situation a few years ago – which I still do not remember specifically – and that Genesis had been exploring ways to make the challenge diet a bit more attractive to rats and mice while still staying within the limits on particle sizes that are specified in the OPP protocols. He said that Genesis has recently concluded that the freshness of the corn is a more important factor than any slight changes in particle size and so has reverted to the practice of aiming directly at the protocol ratios and using the same challenge diet for both rats and mice.)

Baroch (2002b) reportedly followed the "one-day" version of OPP Protocol 1.210, the procedure recommended for screening for efficacy anticoagulant baits for which claims for controlling house mice in a single night's feeding are sought. According to the option of this protocol that Baroch

(2002b) chose to follow, single-sex subgroups of 5 group-caged mice (in cages with wire-mesh bottoms) were exposed to the toxic bait plus OPP rat and mouse challenge diet for one 24-hr period, after which the bait is removed and the subjects' consumption of challenge diet and their general health are to be recorded until the animals die or at least 10 post-exposure days elapse. Each test of the 2 test groups included 2 such male subgroups and 2 such female subgroups, with the wrinkle that "One cage held 6 male mice for 2 days due to an error when the mice were transferred." A 20-animal control group (comprised of 2 male and 2 female subgroups) was to be monitored concurrently to the test group but was fed only OPP challenge diet for the "exposure" and follow-up periods.

Animal weights at the start of the 3-day acclimation period preceding the bait-exposure period are summarized below for the 3 groups of mice.

GROUP	SEX	INITIAL BODY WEIGHTS	
		Mean	Range
Control	Males	25.1	23.7-28.1
	Females	20.4	19.0-22.5
Rep. I	Males	24.8	22.8-26.4
	Females	21.6	20.2-23.7
Rep. 2	Males	25.4	21.8-27.9
	Females	21.5	19.0-26.2

These weights and weight differences between sexes are within the requirements of Protocol 1.210.

During the bait exposure period, Baroch (2002b) attempted to balance the effects of feed container position preferences by starting one subgroup of each sex with cup holding bait (60 g) on the left side of the cage and the one holding challenge diet (60 g) on the right, with the other subgroups of the same sex having the two diets deployed in the opposite positions. Twelve hours into the bait-exposure period, the positions of the containers were reversed in each cage. After the bait-exposure day, test group rats were offered challenge diet only for the rest of their lives. Baroch used paper plates positioned under food containers (and presumably under the wire cage bottoms) to catch spillage. Genesis adopted that procedure after experiencing problems with recovering spillage and assigning what was recovered to diet and cage.

Results of this study are summarized in Table 7. Taken from raw data sheets appended to the report, these data show that all test-group mice died 3-8 days after the start of the bait-exposure day. As subgroups, mice exposed to bait lost weight as a result of that experience, with Rep. I males being 21.0-25.5 g, Rep. I females being 13.6-21.0 g, Rep II males being 17.7-24.8 g, and Rep. II females being 15.6-20.4 g when they were found dead. (As Baroch (2002b) did not mark mice individually, he could not link initial and final weights to individuals. On the other hand, not one of his subjects bled at an ear-tag site.)

The most commonly reported initial symptoms of toxicosis reported for test-group mice were droopy eyelids and hyporeactivity. External hemorrhaging was not reported.

Control-group mice all survived and, according to Baroch (2002b), "appeared normal and healthy at day 10 of the post-test observation period." At study termination, males weighed 25.5-28.7 g and females 18.5-23.8 g. At least 4 of these females lost weight.

Composite bait acceptance was below 33% in and both replicates and in 3 of 4 gender subgroups and in 7 of 8 5-mouse cages. Mean bait consumption was 0.82 g/mouse in Rep I (1.09 g/male and 0.55 g/female) and 1.18 g/mouse (1.38 g/male and 0.97 g/female) in Rep. II. For 25-g males, mean dosages within cages would have been 1.72-3.44 mg/kg body weight. For 20-g females, mean dosages would have been 0.98-2.70 mg/kg. These figures exceed published acute oral LD_{50} values for Brodifacoum for house mice (e.g., the "0.4-0.86" mg/kg range cited by Timm, 1994, in Prevention and Control of Wildlife Damage, p. G-28). That means that the bait could well have killed these mice if they shared it relatively equally. Nevertheless, the relatively poor bait acceptance on Day I suggests that there could be product performance problems for the test bait in real-world mouse control situation. Although the 33% minimum composite bait acceptance criterion that applies in multiple-day tests of anticoagulant baits does not apply for one-day tests, the data reported by Baroch (2002b) suggest that there is ample room for improving the palatability of this bait.

Test room temperatures during the bioassay ranged from 19-26°C (66-79°F), running just beyond the 20-25°C range specified in Protocol 1.210. The 25°C level was exceeded on 7 days, including the two days 1/11/01 and 1/12/01 when the toxic bait was added and removed, respectively, from the test-group cages and on 5 days during the pre-test holding and acclimation periods. The daily low temperature was below 20°C on 2 days during the pre-test holding and acclimation periods. Daily fluctuations in temperature were 1-6 C°.

Relative humidity ranged from 39% to 63% during the bioassay, which actually is pretty good performance for Genesis Laboratories. The relative humidity was within the required range at least some of the time on 17 of the 21 study-relevant days with the daily high never being less than 45%.

The Baroch (2002b) trial was run well enough to be considered acceptable methodologically. The test bait apparently killed all mice exposed to it, thereby exceeding the criterion of 90% mortality in Protocol 1.210. Additional documentation seems to be needed to establish wether the test material used in this study corresponded in composition to the bait described by the pending CSF for 3282-65, which may be the only one of the 4 products considered herein for which the 3/32"-diameter pellet is used. Once that documentation is accepted, no additional efficacy data will be needed for whatever the formulation turns out to have been, when it is used to control house mice in "loose-bait" applications including manually opened Mouse Prufe II cardboard wedges.

With the acceptance of the Baroch (2002a) item (MRID#458121-10), the 3/16" pellets bait used in that study also would need no further rat efficacy data for use as a loose-bait, including application in opened 3-oz d-Con trays (presumably for 3282-66). As that study had a one-day bait-exposure period, it also is adequate to support a "single-night's feeding" claim for the test material that was used.

For the limited purpose of establishing that rats are likely to chew through the placepack material used in the study to access the bait used in the study, the Stafford (2002c) study (MRID# 458121-12) would suffice. Thus, commensal rat claims could be accepted (retained, actually) for 3282-74.

There are no rat efficacy data among the items considered in this review that would seem to be relevant to the ready-mixed product (3282-81) which used to be made of crumbled pellets and which might now be going to be 3/32"-diameter pellets. If the latter were true, the Baroch (2002b) study (MRID# 458121-11) would support house mouse claims for it, if the formulation to be used for 3282-81 in the future matched that used in the Baroch (2002b) study.

The Stafford (2002d) and Stafford (2002e) studies, respectively MRID## 458121-09 and 458121-09, with the 3/32"-diameter pellets failed for reasons of product performance and laboratory

performance. However, the "one-day" trial by Baroch (2002b) essentially saved the day for the mouse claim for the smaller pellet.

The Stafford (2002f) placepack penetration study (MRID# 458121-13) is the only one of the mouse trials submitted by RB for this review in which the 3/16"-diameter pellets were used. That study was performed poorly, especially in the area of caging (60% below the minimum with different subgroups being set apart by partitions within a single tub that was too small for a whole subgroup to being with). If RB were able to show that the 3/16" pellets were effective against house mice through a study of good quality (i.e., better than anything I have seen from Springborn Smithers to date), the Stafford (2002f) could be accepted (basically as a favor) for the limited purpose of establishing placepack penetration.

Summarizing, house mouse efficacy data are needed for the 3/16"-diameter pellet and whatever is to be used in 3282-81, unless it is the 3/32" pellets; and rat efficacy data are needed for whatever is to be used in 3282-81. For any of these studies to be applied to the pending CSFs for these products, RB will have to document that the test baits were essentially identical to them. To my knowledge, they have yet to do so.

We may expect RB to counter with an argument along the lines of, '3/16", 3/32", what's the difference?' The difference is that the larger one is a bit more of a rat size and the smaller one more of a mouse size. With acceptance and mortality scores being as borderline (Baroch) and peculiar (Stafford) I have indicated here, with abundant evidence of marginal feeders, switching particle size could tip the balance toward failure for one target species or the other. In his letter, of 11/26/02, McNear stated that all 3282-65, 3282-66, 3282-74, and 3282-81"share the same efficacy reports. Although not all of the reports are applicable to each product, I feel that all of these studies should be discussed in the individual responses that EPA makes to RB concerning its submissions of 11/26/02.

201.3 Labeling

The proposed revised labels submitted for 3282-65 on 11/26/02 are very much like those accepted by EPA on 2/29/02. The product is proposed to remain limited to indoor use in areas not accessible to children, pets, or other nontarget animals. From the standpoint of efficacy, the only change needed to these labels is a slight adjustment to the modified "single-feeding" claim, namely changing "single-feeding" to "single night's feeding" so as to clarify a potentially misleading element to the claim. For the package of 4 wedges, we should make it clear once again which mouse graphic we have accepted for this product.

Certain label embellishments have been added to these labels. In one way or another, most of these changes pertain to potential hazards associated with the product. One such change appears in the ""**DIRECTIONS FOR USE**" and consists of a sentence in the "**READ THIS LABEL:**" subsection which refers readers to the NPTN's 800 number "For information on this pesticide product". Often, I doubt whether clearing houses have much, if any, specific information on individual pesticide products. In the case of Mouse Prufe II, however, I would expect that any clearinghouse for pesticide incidents would have information on the product because it has been involved in many thousands of incidents, largely because of its extensive penetration of the rodenticide market and somewhat because of the nature of Brodifacoum. If all users of the product would read and heed the limitations on acceptable product use which appear on the current accepted labels for 3282-65, very few incidents would occur (with the product's market share also declining, perhaps). From 1996 until very recently, Mouse Prufe II was being sold with labeling that EPA had not accepted for it. This practice began to change after New York State refused to renew the product's State registration due to that problem.

Among the other safety-related changes is one that I find to be quite disturbing. In the "**NOTE TO PHYSICIANS AND VETERINARIANS**", the following sentence has been added: "Contains Brodifacoum, an anticoagulant with a half-life in the dog or 1 - 4 days." If not false,

that statement is dangerously misleading. While the plasma half-life for this compound might be on the order of 1-4 days, Brodifacoum hangs around in the body for much longer (especially in the liver). Although some of Brodifacoum's various proponents have argued that liver half-lives are not significant toxicologically, symptom rebound has been observed in dogs which have been exposed to Brodifacoum and have been treated acutely with Vitamin K_1. Some time after positive responses to such treatment, dogs have once again shown symptoms of anticoagulant poisoning. This is why labels for Brodifacoum products have advised that Vitamin K_1 administration may have to me maintained for "up to 30" days. Elevated prothrombin times may last longer than that, depending upon the initial dosage. Although this subject is "out of my area", I feel that I cannot in good conscience let the "1 - 4 days" sentence pass without comment.

I did not find any claim pertaining to the control of Warfarin-resistant house mice on the pending labels for 3282-65. I did find an "**ENVIRONMENTAL HAZARDS**" section which seems inappropriate for a product that is limited by its labeling to indoor use (where the phrase "mean high-water mark" might best refer to the bath tub). With all of the misuse that has occurred with this product, I supposed it would be just as well to keep this section (assuming that it does not give anyone "ideas").

The proposed revised labels for 3282-66 differ in many ways from the label that IRB accepted for this product on 1/5/99. Some proposed changes represent improvements and will not be discussed in this review. I will note that claims for control of Warfarin-resistant Norway rats and house mice appear on the proposed revised labels for the "**12 OZ BOX**" and the "**3 OZ. BAIT TRAY**". (Why any promotional claims should appear on the bait trays is something of a mystery as they are not to be sold individually.)

The "**DIRECTIONS FOR USE**" section of the "**12 OZ BOX**" label bears a variety of changes from the current text which appear to have been inspired by comments in the Rodenticide Cluster RED and/or in various deliberations that occurred pursuant to that RED. Under "CONCLUSIONS", I indicate how the use directions should be changed from the standpoints of efficacy and responsible use.

The labels for 3282-66 also bear the "1 - 4 days" half-life statement in the "**NOTE TO PHYSICIANS AND VETERINARIANS**". I hope that no one in OPP has bought off on it.

Because it is a placepack product, 3282-74 has labeling issues that are slightly different from those for 3282-65 and 3282-66. However, the changes that are needed for 3282-74 are nearly the same as for those other two products. RB proposes to include a full set of "**DIRECTIONS FOR USE**" on the 1-oz placepack that is to be used to control rats and mice and what amounts to a complete house mouse set on the propose mouse-only placepack label. RB proposes that the package of size 1-oz placepacks bear mouse-only labeling. Consequently, no qualifying statements will be needed for that label.

As the labeling issues for 3282-81 are almost identical to those for 3282-66, I will not discuss them here. Under "CONCLUSIONS", I indicate the label changes that should be made for all 4 of these products.

202.0 CONCLUSIONS

All 4 Products

1. Of the 8 efficacy reports included in your reregistration applications of November 26, 2002, for your Brodifacoum bait products 3282-65, 3282-66, 3282-74, and 3282-81, the following are acceptable:

   a. the report (MRID# 458121-10) by Baroch (2002a); and

b. the report (MRID# 458121-11) by Baroch (2002b).

These studies are considered to be applicable to the bait formulations and particle sizes that served as test materials. Thus, the Baroch (2002a) study indicates adequate performance of the 3/16"-diameter pellet used in it and, because the bait exposure period was limited to one 24-hr period, also supports a "single night's feeding" rat claim for that specific bait. The Baroch (2002b) study supports house mouse claims and a "single night's feeding" claims for house mice for the 3/32"-diameter pellet that reportedly was used in that study.

For the limited purpose of indicating that commensal rats are likely to chew through the placepack material used to access the bait inside it, the report (MRID# 458121-12) also would be adequate.

As yet, we do not have documentation of the specific compositions of the baits that served as test materials in the accepted studies nor do we have documentation of the composition of the placepack material associated with the MRID# 458121-12 study. Therefore, their relevance to the pending Confidential Statements of Formula (CSFs) and particle sizes for the various Brodifacoum bait products registered to you has not been established. You must provide a submission which indicates exactly how each of the batches of test baits used in the 3 studies mentioned above was formulated and what the pellet diameter was for that test bait. You also must indicate the particle sizes and types that you intend to use for these bait products. It seems to us that you intend to use 3/16"-diameter pellets for 3282-66 and 3282-74, and to use 3/32"-diameter pellets for 3282-65. Please confirm or correct these assumptions and indicate specifically the type of particles and mean particle size that are to be used for 3282-81. Historically, we have not allowed "bridging" of efficacy data between pellet sizes or between pellets and meal baits of identical formulations. Considering the rather borderline results and the abundant evidence of marginal feeders in the studies that we have accepted, we see no good grounds for making exceptions to our practice with respect to these studies.

2. The other 5 efficacy studies submitted on November 26, 2002, for these four products and, because of shortcomings in procedures and/or performance, cannot be "rehabilitated". If it were paired with a new choice-feeding laboratory efficacy trial (e.g., Protocol 1.204 or the "one-day" version of Protocol 1.210) of good quality and appropriate results, the mouse placepack-penetration study (MRID# 458121-13) by Stafford (2002f) could serve the limited purpose of indicating that house mice are likely to penetrate the placepack material used in that study to obtain bait. The placepack material used in that study would have to be documented as the inference drawn would pertain only to that material.

The Norway rat efficacy trials run by Springborn Smithers Laboratories (MRID## 458121-06 and 458121-07) are not acceptable. Along with various procedural shortcomings, the data on bait and challenge diet consumption were compromised in the study (Stafford 2002a) to which we assigned MRID# 458121-07. As that study has an applicable "acceptance" criterion which the data reported failed to meet, it would not have been accepted even if it were free of other problems. Although better acceptance results were reported for the study that we assigned MRID# 458121-06 (Stafford, 2002b), that study failed to meet the mortality requirement. While we are not convinced that the problems with determining bait and challenge diet consumption were solved for the second study, we should observe that results of substandard mortality with a well accepted bait typically occur if the bait is grossly underformulated or if there is a relatively high incidence of marginal feeders in the test groups. The latter seems to have been the case in the Stafford (2002b) study, in which 7 of 40 (18%) rats in the two test groups consumed 3.3 g of bait or less with 6 of those animals surviving.

The mouse choice-feeding studies (MRID## and 458121-08 and 458121-09) also were not acceptable. As acknowledged in the report by Stafford (2002d), there were problems with

the feed consumption data in the study assigned MRID# 458121-09. Although the author was of the opinion that the consumption data obtained was skewed in favor of the challenge diet, thereby artificially deflating the acceptance score, we were less sure of that interpretation than we were that the procedures used were flawed. Putting sand in the feed containers -- reportedly separated from feed by foil -- might also have compromised the efficacy data and (conceivably) could have added to the effectiveness of the ingested anticoagulant. In the Stafford (2002e) study (MRID# 458121-08), steps were taken to improve the accuracy of the feed consumption data collected, and composite acceptance scores of 49.4% and 59.2% were reported for the two test groups. However, only 65% and 60% of the bait-exposed mice died in the two replications. Again, a high incidence of marginal feeders appeared to be the culprit. Fifteen of 40 mice (38%) survived exposure to the brodifacoum bait and all of these animals accepted the toxic bait at 22% of total reported feed intake or less. Thirteen of the surviving mice reportedly ate less than a gram of toxic bait and accepted it at less than 10% of total feed intake. As composite acceptance was on the low side of desirable for the mouse study that was accepted (Baroch 2002b), it seems likely that rejection of the bait by individual CD-1 mice is a significant problem with the bait. If it also is a problem with wild-type *Mus musculus*, successive uses of the bait would be expected to yield diminishing returns as the prevalence of "rejectors" and their offspring increases in the local population.

The mouse placepack penetration study (MRID# 458121-13) was run with group-caged subjects in enclosures that were two small to begin with and then were divided in half. As a result, each subgroup occupied an enclosure that was about 60% smaller than the minimum size indicated in the relevant protocol (1.218) for group-caged mice. Incomplete separation of one side from the other in this arrangement might have been a factor in the assumed cross contamination which led to the death of 2 or 3 mice from the control group in the aborted first attempt at running this study. Whether cross contamination occurred in the second attempts does not seem to be addressed in the report, although there are no results reported that suggest that such was the case.

3. It appears that the personnel at the Springborn Smithers Laboratories involved in these studies were competent researchers but were unfamiliar with rodent efficacy testing procedures and related considerations. Our personnel had offered assistance with the designing of these studies and had urged laboratory and Reckitt Benckiser personnel to submit the results of the first completed study for examination by EPA before others were undertaken. Had that occurred, some of the Springborn Smithers studies might have been fully acceptable. Before that facility conducts additional efficacy studies for you, you should discuss with them various elements of testing including, but not limited to, the following:

   a. the need to improve methods for collecting spilled feed;

   b. the need to ensure that equal numbers of males and females are assigned to groups;

   c. the need to acquire the capacity to produce OPP rat and mouse challenge diet in-house so as to have control of it throughout the entire research endeavor;

   d. the importance of summarizing results by group and by gender within groups;

   e. the desirability of using Swiss Webster strain mice or wild-type animals in house mouse studies;

   f. the need to find a procedure for marking animals that would not appear to potentiate the effects of anticoagulant rodenticides (i.e., not ear-tagging or toe-clipping); and

g. the need to weigh feed containers before and after they are loaded each time they are used (as opposed to loading plastic bags with "precise" amounts of diet and assuming that all is reliably transferred to the container which maintains a constant weight itself).

Laboratory personnel may contact Dr. William Jacobs at 703-305-6406 if they wish to discuss procedures further.

4. The item (MRID# 00042578) cited to support the claim of efficacy against Warfarin-resistant house mice is a resubmission of a study that was originally submitted in 1980 and assigned Accession# 243576. That report is of a 10-animal trial which supports the claim when considered in conjunction with other data submitted in 1978 in a package that was assigned the Accession# 234660.

[NOTE TO ADMINISTRATIVE REVIEWER: DELETE THE PRECEDING PARAGRAPH IF IT IS DETERMINED THAT DISCLOSURE OF UNCITED MRID OR ACCESSION NUMBERS TO THIRD PARTIES IS NOT APPROPRIATE.]

5. Results of bait assays included in the aforementioned efficacy reports suggest that the proposed certified limits which appear on the CSFs of "11/25/02" for your Brodifacoum bait products are too broad. As we have no information on hand which indicates that the data that we requested more than a decade ago to support requests to expand the certified limits for your Brodifacoum baits ever were submitted, we remain of the view that the proposed range is too broad and that something along the lines of 0.0045-0.0060% would be more appropriate.

<u>3282-65</u>

6. Our acceptance of the Baroch (2002b) study (MRID# 458121-11) means that the bait formulation and particle size (reportedly 3/32"-diameter pellets) used in that study would be acceptable for future use in 3282-65. If that bait were shown to be used in 3282-65, no additional efficacy studies would be required for Mouse Prufe II as long as its label continued to direct users to open the wedge boxes upon placement for use. That having been said, we would be remiss if we did not observe that there appeared to be palatability problems with the test bait(s), at least with some mice. You should consider improving this bait.

7. Make the changes listed below to the label for the "<u>1.5 oz and 3.0 oz sizes</u>" that was submitted on November 26, 2002.

   a. Change the modified single-feeding claim on the front panel to read as shown below.

      House Mice may consume a lethal dose in a single night's feeding with first dead mice appearing 4 or 5 days after feeding begins.

   b. In the "**NOTE TO PHYSICIAN AND VETERINARIAN**" change the sentence "Contains Brodifacoum, an anticoagulant with a half-life in the dog of 1 - 4 days" to something which is neither false nor misleading. If that half-life range were correct and the whole story, there would be no need to continue Vitamin K_1 administration "for up to 30 days". As prolonged prothrombin times and symptom rebound have been demonstrated for Brodifacoum, treatments for 30 days or more have been needed in clinical situations. Therefore, the impression created by the half-life statement (even if accurate for something like plasma) is misleading and potentially dangerously so.

8. On the label for the "<u>6oz (170g) Outer Carton (4/1.5oz wedges</u>" package, make the same changes as are noted above for the "<u>1.5 oz and 3.0 oz sizes</u>". Note also that the "Graphic - Mouse" that is to appear on the front panel must be the graphic that we

accepted in our letter of January 26, 2002, and must be used in accordance with the conditions of acceptance indicated in that letter.

3282-66

6. Our acceptance of the Baroch (2002a) study (MRID# 458121-10) means that the basic label claims for controlling commensal rats and house mice are acceptable for the bait formulation and particle size (reportedly 3/16"-diameter pellets) used in that study. If that bait were shown to be used in 3282-66, no additional efficacy studies would be required to support rat claims for "**d-CON® PELLETS GENERATION II**" as long as labels continue to direct users to open the bait trays upon deployment. Although the rat claims are accepted, the fairly high incidence of marginal feeders in the Baroch (2002a) study, and perhaps in the others, suggest that the test material could be improved upon.

   Mouse claims are not supported for the 3/16"-diameter pellet by studies reported in the efficacy data packages submitted on November 26, 2002.

7. Make the changes listed below to the label for the "**12 OZ BOX**" that was submitted on November 26, 2002.

   a. Change the modified single-feeding claim on the front panel to read as shown below.

      Norway rats and house mice may consume a lethal dose in a single night's feeding with first dead rodents appearing 4 or 5 days after feeding begins.

   b. In the "**NOTE TO PHYSICIAN AND VETERINARIAN**" change the sentence "Contains Brodifacoum, an anticoagulant with a half-life in the dog of 1 - 4 days" to something which is neither false nor misleading. If that half-life range were correct and the whole story, there would be no need to continue Vitamin K_1 administration "for up to 30 days". As prolonged prothrombin times and symptom rebound have been demonstrated for Brodifacoum, treatments for 30 days or more have been needed in clinical situations. Therefore, the impression created by the half-life statement (even if accurate for something like plasma) is misleading and potentially dangerously so.

   c. Change the "**USE RESTRICTIONS:**" subsection of the "**DIRECTIONS FOR USE**" to read as indicated below.

      USE RESTRICTIONS: This product may be used to control Norway Rats, Roof Rats, and House Mice indoors and against the outside walls of homes, industrial, commercial, agricultural, and public buildings. d-Con® Pellets Generation II also may be used in transport vehicles (ships, trains, aircraft) and in and against the outside walls of related port or terminal buildings. All outdoor placements must be made in tamper-resistant bait stations. Do not use this product in sewers. Do not use this product in food or animal feed areas. Do not contaminate human or pet food areas. Do not place bait near or inside ventilation duct openings. Do not broadcast bait.

   d. Delete "in or beside burrows," from the second sentence of the "**SELECTION OF TREATMENT AREAS:**" subsection. This product is inappropriate for use in burrows. An instruction to place bait beside burrows might be interpreted by some as an exception to the requirements which limit external placements to locations against outside walls and require external placements to be in tamper-resistant bait stations.

e. Under "**APPLICATION DIRECTIONS:**", change "rodent activity" to "rat activity" in the third sentence of the inset paragraph entitled "**To Control Norway and Roof Rats:**".

f. Insert the heading "**Follow-Up:**" at the beginning of the last paragraph of the "**APPLICATION DIRECTIONS:**" subsection.

g. Submit a copy of the "Graphic - Rodent" that is to appear on this label. The rodent depicted must not be of a species that is not claimed on this label. The graphic may not depict any bait application that is inconsistent with the label's required text or that might be interpreted as being so.

8. On the label for the "**3 OZ. BAIT TRAY**", change the modified single-feeding claim and the "**NOTE TO PHYSICIAN AND VETERINARIAN**" in the same ways as are indicated above for the label for the "**12 OZ BOX**". To accommodate the text that has been added to the precautionary sections, you should consider deleting promotional claims (e.g., "Solving America's Rodent Problems ..." and "SATISFACTION GUARANTEED ...") from the label for the bait trays. As those trays are not to be sold individually and traditionally have had text which contrasts rather poorly with the background color, it is difficult to see much value to having the promotional claims on the tray labels.

3282-74

6. Our acceptance of the Baroch (2002a) study (MRID# 458121-10) means that the basic label claims for controlling commensal rats and house mice are acceptable for the bait formulation and particle size (reportedly 3/16"-diameter pellets) used in that study. If that bait were shown to be used in 3282-74, the requirement for a choice feeding efficacy study to support rat claims would be met. Due to our limited-purpose acceptance of the rat placepack-penetration study (MRID# 458121-12) by Stafford (2002c), there would be no additional efficacy data required to support claims that the same bait would control commensal rats when used in placepacks made of the particular material that comprised those tested by Stafford (2002c). Still, the data reviewed suggest room for improvement of this bait.

   With regard to house mouse claims, however, we note that data showing the effectiveness of the 3/16"-diameter pellets against this species were not submitted. Therefore, any possible application of the seriously flawed placepack penetration study (MRID# 458121-13) by Stafford (2002f) to the "penetration" part of the house mouse claim is put on hold until data from an appropriate choice feeding study are submitted and accepted.

7. The comments immediately below apply to the labels for the "**20/1.0 oz Bait Pack Outer Box**" and the "**1.0 oz Bait Pack (for mice and Rats)**" submitted on November 26, 2002.

   a. Change the modified single-feeding claim on the front panel to read as shown below.

      Norway rats and house mice may consume a lethal dose in a single night's feeding with first dead rodents appearing 4 or 5 days after feeding begins.

   b. The only "Graphic - Rodent" that may appear on this product's labeling is the one that we indicated would be acceptable in our letter of January 26, 2002. Only a depiction of a house mouse may appear on labels for mouse-only "presentations" of this product.

   c. In the "**NOTE TO PHYSICIAN AND VETERINARIAN**" change the sentence "Contains Brodifacoum, an anticoagulant with a half-life in the dog of 1 - 4 days" to

something which is neither false nor misleading. If that half-life range were correct and the whole story, there would be no need to continue Vitamin K_1 administration "for up to 30 days". As prolonged prothrombin times and symptom rebound have been demonstrated for Brodifacoum, treatments for 30 days or more have been needed in clinical situations. Therefore, the impression created by the half-life statement (even if accurate for something like plasma) is misleading and potentially dangerously so.

d. Change the "**USE RESTRICTIONS:**" subsection of the "**DIRECTIONS FOR USE**" to read as indicated below.

> **USE RESTRICTIONS:** This product may be used to control Norway Rats, Roof Rats, and House Mice indoors and against the outside walls of homes, industrial, commercial, agricultural, and public buildings. d-Con® Bait Pellets II also may be used in transport vehicles (ships, trains, aircraft) and in and against the outside walls of related port or terminal buildings. All outdoor placements must be made in tamper-resistant bait stations. Do not use this product in sewers. Do not use this product in food or animal feed areas. Do not contaminate human or pet food areas. Do not place bait near or inside ventilation duct openings. Do not broadcast bait.

e. In the second sentence of the "**SELECTION OF TREATMENT AREAS:**" subsection, change "in or beside burrows" to "in burrows".

f. Under "**APPLICATION DIRECTIONS:**", change "rodent activity" to "rat activity" in the third sentence of the inset paragraph entitled "**To Control Norway and Roof Rats:**".

h. Change the heading for the third paragraph of the "**APPLICATION DIRECTIONS:**" subsection from "**For Rats and Mice:**" to "**Follow-Up**".

8. The comments immediately below apply to the labels for the "<u>6/1.0 oz Bait Pack Outer Box</u>" and the "<u>1.0 oz - Bait Pack (for Mice)</u>" submitted on November 26, 2002, which we assume will continue to be limited to mouse-only labeling.

a. Change the modified single-feeding claim on the front panel to read as shown below.

> House Mice may consume a lethal dose in a single night's feeding with first dead mice appearing 4 or 5 days after feeding begins.

b. The only "Graphic - Rodent" that may appear on this product's labeling is the one of a house mouse that we indicated would be acceptable in our letter of January 26, 2002. Only a depiction of a house mouse may appear on labels for mouse-only "presentations" of this product.

c. In the "**NOTE TO PHYSICIAN AND VETERINARIAN**" change the sentence "Contains Brodifacoum, an anticoagulant with a half-life in the dog of 1 - 4 days" to something which is neither false nor misleading.

d. Change the "**USE RESTRICTIONS:**" subsection of the "**DIRECTIONS FOR USE**" to read as indicated below.

> **USE RESTRICTIONS:** This product may be used to control House Mice indoors and against the outside walls of homes, industrial, commercial, agricultural, and public buildings. d-Con® Bait Pellets II also may be used in transport vehicles (ships, trains, aircraft) and in and against the outside walls of related port or terminal buildings. All outdoor

placements must be made in tamper-resistant bait stations. Do not use this product in sewers. Do not use this product in food or animal feed areas. Do not contaminate human or pet food areas. Do not place bait near or inside ventilation duct openings. Do not broadcast bait.

e. In the second sentence of the "**SELECTION OF TREATMENT AREAS:**" subsection, change "In or beside burrows" to "In burrows".

3282-81

6. Until the form and pellet size of the bait used in this product is documented to us, we cannot determine whether any accepted efficacy study is applicable to the product as you have made it or propose to make it.

7. Make the changes listed below to the label for the "**12 OZ AND 3 LB. OUTER BOX**" that was submitted on November 26, 2002.

a. Change the modified single-feeding claim on the front panel to read as shown below.

Norway rats and house mice may consume a lethal dose in a single night's feeding with first dead rodents appearing 4 or 5 days after feeding begins.

b. In the "**NOTE TO PHYSICIAN AND VETERINARIAN**" change the sentence "Contains Brodifacoum, an anticoagulant with a half-life in the dog of 1 - 4 days" to something which is neither false nor misleading. If that half-life range were correct and the whole story, there would be no need to continue Vitamin K_1 administration "for up to 30 days". As prolonged prothrombin times and symptom rebound have been demonstrated for Brodifacoum, treatments for 30 days or more have been needed in clinical situations. Therefore, the impression created by the half-life statement (even if accurate for something like plasma) is misleading and potentially dangerously so.

c. Change the "**USE RESTRICTIONS:**" subsection of the "**DIRECTIONS FOR USE**" to read as indicated below.

USE RESTRICTIONS: This product may be used to control Norway Rats, Roof Rats, and House Mice indoors and against the outside walls of homes, industrial, commercial, agricultural, and public buildings. d-Con® Ready Mixed Baitbits also may be used in transport vehicles (ships, trains, aircraft) and in and against the outside walls of related port or terminal buildings. All outdoor placements must be made in tamper-resistant bait stations. Do not use this product in sewers. Do not use this product in food or animal feed areas. Do not contaminate human or pet food areas. Do not place bait near or inside ventilation duct openings. Do not broadcast bait.

d. Delete "In or beside burrows," from the second sentence of the "**SELECTION OF TREATMENT AREAS:**" subsection. This product is inappropriate for use in burrows. An instruction to place bait beside burrows might be interpreted by some as an exception to the requirements which limit external placements to locations against outside walls and require external placements to be in tamper-resistant bait stations.

e. Note that the two qualifying sentences which appear directly under the subsection heading "**APPLICATION DIRECTIONS:**" are to be used only on the 12-oz box.

f. Under "**APPLICATION DIRECTIONS:**", change "rodent activity" to "rat activity" in the third sentence of the paragraph entitled "**To Control Norway and Roof Rats:**".

g. Insert the heading "**Follow-Up:**" at the beginning of the last paragraph of the "**APPLICATION DIRECTIONS:**" subsection.

g. Submit a copy of the "Graphic - Rodent" that is to appear on this label. If realistic, rodent depicted must not be of a species that is not claimed on this label. The graphic may not depict any bait application that is inconsistent with the label's required text or that might be interpreted as being so.

8. On the label for the "**3 OZ. BAIT TRAY**", change the modified single-feeding claim and the "**NOTE TO PHYSICIAN AND VETERINARIAN**" in the same ways as are indicated above for the label for the "**12 OZ BOX AND 3 LB. OUTER BOX**". To accommodate the added text to the precautionary sections, you should consider deleting promotional claims (e.g., "Solving America's Rodent Problems ..." and "SATISFACTION GUARANTEED ...") from the label for the bait trays. As those trays are not to be sold individually and traditionally have had text which contrasts rather poorly with the background color, it is difficult to see much value to having the promotional claims on the tray labels.

William W. Jacobs
Biologist
Insecticide-Rodenticide Branch
February 2, 2004

Table 1. Rat "1-day" laboratory efficacy data for "Test Substance Fromula 4-PA-165 (Brodifacoum 50 ppm)", Replication I (MRID #458121-10).

TEST #	SUBJ. #	SEX	BAIT EATEN	EPA DIET EATEN	ACCEPTANCE	MORTALITY	DEATH DAY
01024	1	M	0.4	22.7	1.7%	0	-
	5	M	18.5	11.8	61.1%	1	6
	10	M	6.2	22.7	21.5%	1	7
	11	M	8.8	20.3	30.2%	1	6
	12	M	0.3	27.3	1.1%	1	9
	13	M	2.9	29.5	9.0%	1	3
	15	M	19.6	9.9	66.4%	1	3
	27	M	7.8	21.1	27.0%	1	6
	28	M	6.4	22.2	22.4%	1	3
	30	M	4.3	25.7	14.3%	1	5
Males Mean	10	M	75.2	213.2	26.1% 25.5%	90%	3-9

TEST #	SUBJ. #	SEX	BAIT EATEN	EPA DIET EATEN	ACCEPTANCE	MORTALITY	DEATH DAY
01024	33	F	5.9	22.1	21.1%	1	4
	34	F	16.0	10.6	60.2%	1	4
	36	F	17.9	11.6	60.7%	1	4
	38	F	8.2	16.6	33.1%	1	3
	42	F	5.5	21.1	20.7%	1	4
	52	F	4.7	23.3	16.8%	1	6
	55	F	12.7	18.9	40.2%	1	4
	58	F	3.7	23.5	13.6%	1	6
	59	F	8.1	23.4	25.7%	1	2
	60	F	0.8	25.7	3.0%	0	-
Females Mean	10	F	83.5	196.8	29.8% 29.5%	90.0%	2-6
Both Mean	20	B	158.7	410.0	27.9% 27.5%	90.0%	2-9

Table 2. Rat "1-day" laboratory efficacy data for "Test Substance Fromula 4-PA-165 (Brodifacoum 50 ppm)", Replication II (MRID #458121-10).

TEST #	SUBJ. #	SEX	BAIT EATEN	EPA DIET EATEN	ACCEPTANCE	MORTALITY	DEATH DAY
01024	3	M	12.3	14.6	45.7%	1	7
	4	M	0.4	28.4	1.4%	0	-
	6	M	11.3	23.8	32.2%	1	6
	8	M	3.6	26.3	12.0%	1	3
	9	M	2.4	26.1	8.4%	1	3
	17	M	8.6	21.2	28.9%	1	4
	18	M	1.0	26.5	3.6%	0	-
	21	M	2.5	28.8	8.0%	1	3
	22	M	3.2	24.7	11.5%	1	5
	24	M	16.6	13.6	55.0%	1	2
Males Mean	10	M	61.9	234.0	20.9% 20.7%	80%	2-7

TEST #	SUBJ. #	SEX	BAIT EATEN	EPA DIET EATEN	ACCEPTANCE	MORTALITY	DEATH DAY
01024	31	F	16.8	15.7	51.7%	1	3
	32	F	10.0	15.6	39.1%	1	3
	37	F	8.0	17.9	30.9%	1	6
	39	F	7.2	17.4	29.3%	1	5
	40	F	15.1	7.8	65.9%	1	3
	41	F	10.2	15.5	39.7%	1	3
	43	F	9.5	21.0	31.1%	1	5
	45	F	7.7	20.2	27.6%	1	6
	48	F	8.8	19.3	31.3%	1	4
	49	F	9.6	20.9	31.5%	1	4
Females Mean	10	F	102.9	171.3	37.5% 37.8%	100.0%	3-6
Both Mean	20	B	164.8	405.3	28.9% 29.2%	90.0%	2-7

Table 3a. Rat "15-day" laboratory efficacy data for "Test Substance Fromula 4-PA-165, 3/16- inch diameter", Replication I (MRID #458121-07), from raw data sheets.

TEST #	SUBJ. #	SEX	BAIT EATEN	EPA DIET EATEN	ACCEPTANCE	MORTALITY	DEATH DAY
13760. 4102	9	M	67.2	113.0	37.3%	1	8
	11	M	70.8	67.9	51.0%	1	8
	21	M	20.7	347.8	5.6%	0	-
	23	M	42.3	92.8	31.3%	1	7
	25	M	20.7	112.4	15.6%	1	10
	31	M	92.8	78.4	54.2%	1	7
	35	M	18.8	84.0	18.1%	1	6
	39	M	49.8	64.8	43.5%	1	5
	41	M	35.0	353.9	9.0%	1	16
	49	M	14.0	115.5	10.8%	1	5
Males Mean	10	M	431.9	1430.4	23.2% 27.6%	90%	5-16

TEST #	SUBJ. #	SEX	BAIT EATEN	EPA DIET EATEN	ACCEPTANCE	MORTALITY	DEATH DAY
13760. 4102	6	F	76.9	29.6	72.3%	1	7
	10	F	128.1	90.9	58.1%	1	9
	14	F	117.5	64.7	64.5%	1	8
	26	F	45.2	81.0	35.8%	1	7
	28	F	27.7	98.5	21.9%	1	7
	34	F	20.2	100.3	16.8%	1	7
	36	F	39.8	51.1	43.7%	1	5
	52	F	46.0	54.8	45.8%	1	5
	54	F	86.2	54.7	61.2%	1	7
	60	F	63.1	22.3	73.9%	1	6
Females Mean	10	F	648.5	647.9	50.0% 49.4%	100.0%	5-9
Both Mean	20	B	1080.4	2078.3	34.2% 38.5%	95.0%	5-16

Table 3b. Rat "15-day" laboratory efficacy data for "Test Substance Fromula 4-PA-165, 3/16- inch diameter", Replication I (MRID #458121-07), from "COMPUTERIZED DATA".

TEST #	SUBJ. #	SEX	BAIT EATEN	EPA DIET EATEN	ACCEPTANCE	MORTALITY	DEATH DAY
13760. 4102	9	M	35.0	113.0	23.8%	1	8
	11	M	51.9	67.9	43.3%	1	6
	21	M	7.2	347.8	2.0%	0	-
	23	M	22.6	92.9	19.6%	1	7
	25	M	6.3	112.4	5.3%	1	10
	31	M	35.6	78.4	31.2%	1	7
	35	M	10.8	83.9	11.4%	1	6
	39	M	31.9	64.8	33.0%	1	5
	41	M	8.9	353.9	2.5%	1	16
	49	M	2.4	115.5	2.0%	1	5
Males Mean	10	M	212.8	1430.3	12.9% 17.4%	90%	5-16

TEST #	SUBJ. #	SEX	BAIT EATEN	EPA DIET EATEN	ACCEPTANCE	MORTALITY	DEATH DAY
13760. 4102	6	F	58.8	29.4	66.7%	1	7
	10	F	94.6	90.8	51.0%	1	9
	14	F	62.7	64.7	49.2%	1	6
	26	F	30.2	81.0	27.2%	1	7
	28	F	6.9	98.5	6.3%	1	7
	34	F	5.5	100.3	5.2%	1	7
	36	F	36.1	51.1	41.4%	1	5
	52	F	42.8	54.8	43.9%	1	5
	54	F	61.2	54.7	52.8%	1	7
	60	F	59.4	22.3	72.7%	1	6
Females Mean	10	F	480.2	647.8	41.5% 41.8%	100.0%	5-9
Both Mean	20	B	672.8	2077.9	24.5% 29.6%	95.0%	5-16

Table 4. Rat "15-day" laboratory efficacy data for "Test Substance Fromula 4-PA-165, 3/16- inch diameter", Replication II (MRID #458121-07) from "COMPUTERIZED DATA".

TEST #	SUBJ. #	SEX	BAIT EATEN	EPA DIET EATEN	ACCEPTANCE	MORTALITY	DEATH DAY
13760. 4102	1	M	50.1	67.8	42.5%	1	9
	3	M	110.3	2.4	97.9%	1	8
	13	M	2.4	86.7	2.7%	1	5
	15	M	68.0	20.2	77.1%	1	5
	27	M	72.2	26.1	73.4%	1	7
	29	M	3.9	318.7	1.2%	1	15
	37	M	49.8	114.4	30.3%	1	11
	53	M	15.3	295.0	4.9%	1	15
	57	M	70.6	40.3	63.7%	1	7
	59	M	12.8	189.7	6.3%	1	10
Males Mean	10	M	455.4	1161.3	28.2% 40.0%	100%	5-15

TEST #	SUBJ. #	SEX	BAIT EATEN	EPA DIET EATEN	ACCEPTANCE	MORTALITY	DEATH DAY
13760. 4102	2	F	8.8	181.3	4.6%	1	11
	8	F	35.9	62.5	36.5%	1	7
	12	F	41.0	63.7	39.2%	1	12
	16	F	46.9	43.3	52.0%	1	16
	18	F	46.3	45.4	50.5%	1	7
	20	F	77.7	15.3	83.5%	1	7
	24	F	4.2	107.8	3.8%	1	7
	30	F	94.5	79.5	54.3%	1	15
	44	F	37.7	99.8	27.4%	1	7
	58	F	39.6	45.6	46.5%	1	4
Females Mean	10	F	432.6	744.2	36.8% 39.8%	100.0%	4-16
Both Mean	20	B	888.0	1905.5	31.8% 39.9%	100.0%	4-16

Table 5a. Rat "3-day" laboratory efficacy data for "4-PA-165, 3/16-inch diameter pellets", Replication I (Stafford, 2002b, MRID# 458121-08)

TEST #	SUBJ. #	SEX	BAIT EATEN	EPA DIET EATEN	ACCEPTANCE	MORTALITY	DEATH DAY
13760.4109	3	M	24.8	41.8	37.2%	1	4
	13	M	22.8	18.3	55.3%	1	8
	16	M	8.2	64.4	11.3%	1	5
	23	M	8.8	74.8	10.7%	1	7
	28	M	9.7	87.8	8.2%	1	13
	31	M	2.3	14.8	13.5%	0	-
	37	M	17.2	55.3	23.7%	1	7
	43	M	3.3	63.5	4.9%	0	-
	47	M	43.5	8.9	86.3%	1	7
Males Mean	9	M	134.3	407.2	24.8% 27.8%	78%	4-13

TEST #	SUBJ. #	SEX	BAIT EATEN	EPA DIET EATEN	ACCEPTANCE	MORTALITY	DEATH DAY
13760.4109	6	F	8.4	27.1	23.7%	1	8
	16	F	25.7	39.3	39.5%	1	7
	22	F	36.8	25.1	59.5%	1	8
	24	F	46.8	21.9	69.0%	1	4
	26	F	49.2	8.9	84.7%	1	9
	28	F	48.2	20.5	69.3%	1	8
	38	F	48.1	13.7	77.1%	1	11
	40	F	8.8	35.8	19.8%	1	9
	48	F	1.8	18.8	7.9%	0	-
	52	F	19.0	24.9	43.3%	1	8
	56	F	23.4	27.9	45.8%	1	9
Females Mean	11	F	314.0	283.5	54.4% 49.0%	91%	4-11
Both Mean	20	B	448.3	670.7	40.1% 34.9%	85%	4-13

Table 5b. Rat "3-day" laboratory efficacy data for "4-PA-165, 3/16-inch diameter pellets", Replication II (Stafford, 2002d, MRID #458121-08).

TEST #	SUBJ. #	SEX	BAIT EATEN	EPA DIET EATEN	ACCEPTANCE	MORTALITY	DEATH DAY
13760.4109	5	M	7.3	32.7	18.3%	1	7
	7	M	2.1	27.8	7.0%	0	-
	9	M	8.0	71.7	10.0%	1	7
	17	M	12.8	70.8	15.3%	1	6
	19	M	36.8	36.1	51.7%	1	6
	27	M	36.8	43.9	46.9%	1	7
	45	M	3.3	35.2	8.6%	0	-
	51	M	27.1	61.5	30.6%	1	5
	55	M	3.2	20.8	13.3%	1	9
	57	M	27.2	30.3	47.3%	1	5
	59	M	45.8	42.3	52.0%	1	7
Males Mean	11	M	214.2	473.1	31.2% 27.4%	82%	5-9

TEST #	SUBJ. #	SEX	BAIT EATEN	EPA DIET EATEN	ACCEPTANCE	MORTALITY	DEATH DAY
13760.4109	2	F	46.6	18.7	71.4%	1	7
	4	F	12.5	25.3	33.1%	1	9
	10	F	45.2	20.7	68.6%	1	5
	18	F	48.7	16.2	75.0%	1	7
	30	F	21.7	28.4	43.3%	1	5
	34	F	2.8	18.2	14.7%	0	-
	42	F	19.9	26.9	42.5%	1	10
	46	F	36.3	23.4	62.1%	1	9
	50	F	40.4	29.0	58.2%	1	9
Females Mean	9	F	276.1	204.8	57.4% 52.1%	88.9%	5-10
Both Mean	20	B	490.3	677.9	42.0% 38.5%	85.0%	5-10

Table 6a. Mouse "3-day" laboratory efficacy data for "4-PA-165, 3/32-inch diameter pellets", Replication I (Stafford, 2002a, MRID# 456121-08)

TEST #	SUBJ. #	SEX	BAIT EATEN	EPA DIET EATEN	ACCEPTANCE	MORTALITY	DEATH DAY
13760.4108	3	M	10.1	2.4	80.8%	1	6
	15	M	12.7	3.1	80.4%	1	6
	25	M	9.1	-0.3	103.4%	1	9
	29	M	0.8	13.2	4.3%	0	-
	39	M	0.8	11.5	5.0%	0	-
	43	M	10.3	2.1	83.1%	1	4
	45	M	7.5	0.4	94.9%	1	4
	47	M	7.0	4.1	63.1%	1	8
	51	M	0.7	15.5	4.3%	0	-
	55	M	8.9	0.8	92.5%	1	3
	59	M	6.2	6.2	50.0%	1	5
Males Mean	11	M	74.7	69.0	55.9% 60.2%	73%	4-9

TEST #	SUBJ. #	SEX	BAIT EATEN	EPA DIET EATEN	ACCEPTANCE	MORTALITY	DEATH DAY
13760.4108	2	F	6.5	2.5	72.2%	1	9
	10	F	0.3	9.5	3.1%	0	-
	14	F	5.4	0.0	100.0%	1	7
	20	F	0.8	11.2	6.7%	0	-
	28	F	10.1	1.8	84.9%	1	7
	34	F	0.7	10.1	6.5%	0	-
	36	F	2.3	6.8	25.3%	1	7
	40	F	0.8	11.8	4.8%	0	-
	50	F	8.3	0.5	94.9%	1	7
Females Mean	9	F	36.0	54.2	39.9% 44.3%	56%	7-9
Both Mean	20	B	110.7	113.2	49.4% 53.0%	65%	4-9

Table 6b. Mouse "3-day" laboratory efficacy data for "4-PA-165, 3/32-inch diameter pellets", Replication II (Stafford, 2002a, MRID #456121-09).

TEST #	SUBJ. #	SEX	BAIT EATEN	EPA DIET EATEN	ACCEPTANCE	MORTALITY	DEATH DAY
13760.4108	1	M	0.4	13.9	2.8%	0	-
	5	M	0.8	6.9	8.0%	0	-
	9	M	11.7	0.3	97.5%	1	10
	13	M	10.7	2.4	81.7%	1	9
	19	M	1.4	11.3	11.0%	0	-
	21	M	14.2	0.2	98.6%	1	4
	23	M	12.9	3.3	79.6%	1	8
	27	M	2.6	9.2	22.0%	0	-
	33	M	11.4	0.8	95.0%	1	5
Males Mean	9	M	65.9	48.1	57.8% 55.1%	56%	4-10

TEST #	SUBJ. #	SEX	BAIT EATEN	EPA DIET EATEN	ACCEPTANCE	MORTALITY	DEATH DAY
13760.4108	4	F	10.4	1.5	87.4%	1	8
	8	F	0.5	4.9	9.3%	0	-
	18	F	0.7	9.8	6.8%	0	-
	26	F	12.4	3.4	78.5%	1	4
	38	F	0.4	10.3	3.7%	0	-
	42	F	10.8	-0.1	100.9%	1	9
	46	F	9.7	5.5	63.8%	1	7
	48	F	0.5	9.7	4.9%	0	-
	52	F	11.8	1.3	90.1%	1	5
	58	F	8.7	3.2	73.1%	1	7
	60	F	13.2	2.5	84.1%	1	5
Females Mean	11	F	79.1	51.8	60.4% 54.8%	63.6%	4-9
Both Mean	20	B	145.0	99.9	59.2% 54.9%	60.0%	4-10

Table 7. Swiss Webster strain house mouse "1-day" laboratory efficacy data for 0.005% Brodifacoum Mouse Prufe II (MRID #458121-11).

TEST #	CAGE	SEX	NO. MICE	BAIT EATEN	EPA DIET EATEN	ACCEPTANCE	NUMBER DYING	MORTALITY	DAYS TO DEATH
Replication 1									
00040	A	M	5	4.3	16.0	21.2%	5	100%	4-7
	M	M	5	6.6	14.3	31.6%	5	100%	5-8
Subtotal	A & M	M	10	10.9	30.3	26.5%	10	100%	4-8
00040	B	F	5	1.9	9.7	16.4%	5	100%	6-8
	D	F	5	3.6	14.9	19.5%	5	100%	5-7
Subtotal	B & D	F	10	5.5	24.6	18.3%	10	100%	5-8
TOTALS	A,M,B,D	Both	20	16.4	54.9	23.0% 22.4%	20	100%	4-8
Replication 2									
00040	C	M	5	5.2	12.1	30.1%	5	100%	5-7
	I	M	5	8.6	12.2	41.3%	5	100%	3-6
Subtotal	C & I	M	10	13.8	24.3	36.2%	10	100%	3-7
00040	L	F	5	5.4	12.4	30.3%	5	100%	5-6
	N	F	5	4.3	14.3	23.1%	5	100%	3-8
Subtotal	L & N	F	10	9.7	26.7	26.6%	10	100%	3-8
TOTALS	C,I,L,N	Both	20	23.5	51.0	31.5% 31.4%	20	100%	3-8

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

January 09, 2003

MEMORANDUM:

Subject: EPA Reg. No.: 3282-81/d-Con® Ready Mixed Baitbits
DP Barcode: D287561
Case No.: 2760

From: Maria Rivera Piansay, Chemist
Product Reregistration Branch
Special Review and Reregistration Division (7508C)

06/17/03

MJP

To: Venus Eagle-Kunst, CRM
Product Reregistration Branch
Special Review and Reregistration Division (7508C)

Applicant: Reckitt Benckiser, Inc.
1655 Valley Road
Wayne, NJ 07474

FORMULATION FROM EPA Reg. No. 3282-81 LABEL:

	% by wt.
Active Ingredient(s):	
Brodifacoum: 3-[3-(4'-bromo-[1,1'-biphenyl]-4-yl)-1,2,3,4-tetrahydro-1-napthalenyl]-4-hydroxy-2H-1-benzopyran-2-one	0.005%
Inert Ingredient(s):	99.995%
Total:	100.000%

BACKGROUND:

In the 8 month response to the ***Rodenticide Cluster*** RED, the registrant is citing acute oral, acute dermal, acute inhalation, primary eye irritation, primary dermal irritation and dermal sensitization studies to support the reregistration of EPA Reg. No. 3282-81. The MRID numbers for the cited studies are as follows: 449837-01 (870.1100), 457189-01 (870.1200), 457607-01 (attrition study for 870.1300), 445979-01 (870.2400), 440217-03 (870.2500) and 440217-04 (870.2600).

The acute oral and acute dermal studies were reviewed and accepted by M. Lewis of PRB/SRRD on 10/15/02 and 10/30/02, respectively. The acute inhalation study (attrition study) was found acceptable by PRB/SRRD and the waiver request for acute inhalation was granted. The primary eye irritation, primary dermal irritation and skin sensitization studies were found unacceptable by PRB/SRRD on 03/28/02, however, the studies were categorized and no additional data were required. Refer to the review by M. Lewis of PRB/SRRD dated 10/16/02 (Barcode number D285919) in connection with the acute toxicity requirements for EPA Reg. No. 100-1050. The subject product and EPA Reg. No. 100-1050 are both listed under Batch 2 of the Batching Appendix of the Rodenticide Cluster RED.

RECOMMENDATIONS:

The subject product may cite all acute toxicity studies listed above, to support its reregistration requirements. All acute toxicity requirements for the subject product are satisfied.

The acute toxicity profile for EPA Reg. No. 3282-81 is currently:

Acute Oral	IV	Cited
Acute Dermal	III	Cited
Acute Inhalation	IV	Cited
Primary Eye	IV	Cited
Primary Dermal	III	Cited
Skin Sensitization	Non-sensitizer	Cited

LABELING: (for Homeowner use)

ID #s: 003282-00081 d-CON® READY MIXED BAITBITS

SIGNAL WORD: CAUTION

HAZARDS TO HUMANS AND DOMESTIC ANIMALS:

Harmful if absorbed through skin. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling. Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

FIRST AID:

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

Note to CRM/PM/Registrant:

The proposed label should contain a Note to Physician which addresses the presence of an anticoagulant. The following statements are some suggested types of information that could be included, if applicable:

- technical information on symptomatology;
- use of supportive treatments to maintain life functions;
- medicine that will counteract the specific physiological effects of the pesticide;
- company telephone number to specific medical personnel who can provide specialized medical advice.

LABELING: (for commercial use)

ID #: 003282-00081 d-CON® READY MIXED BAITBITS

SIGNAL WORD: CAUTION

HAZARDS TO HUMANS AND DOMESTIC ANIMALS:

Harmful if absorbed through skin. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling.

FIRST AID:

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

USER SAFETY RECOMMENDATIONS:

Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

Note to CRM/PM/Registrant:

The proposed label should contain a Note to Physician which addresses the presence of an anticoagulant. The following statements are some suggested types of information that could be included, if applicable:

- technical information on symptomatology;
- use of supportive treatments to maintain life functions;
- medicine that will counteract the specific physiological effects of the pesticide;
- company telephone number to specific medical personnel who can provide specialized medical advice.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

April 27, 1999

MEMORANDUM:

Subject: Acute Inhalation Waivers for EPA Reg. No. 3282-74 (d-Con LIM-N8) and 3282-81 (d-Con Ready Mixed Generation II)
Case Name: Brodifacoum
Case No.: 2755

From: Ann Hanger, Environmental Protection Specialist A. Hanger
Product Reregistration Branch
Special Review and Reregistration Division (7508C) MJP

To: Venus Eagle, CRM
Product Reregistration Branch
Special Review and Reregistration Division (7508C)

Applicant: Reckitt & Colman, Inc.
1655 Valley Road
Wayne, NJ 07474

BACKGROUND: In response to the RED for Brodifacoum, Reckitt & Colman requests waivers for the acute inhalation toxicity studies for two Brodifacoum products, EPA Reg. Nos. 3282-74 and 3282-81. The waiver rationale from the registrant is based on the solid, non-friable bait pellet composition of both products, low vapor pressure, supporting acute oral and dermal toxicity studies, and lack of customer call-ins related to inhalation exposure over the last three years. The registrant claims that normal handling of both d-Con products:

- do not generate aerosols, vapors or significant dust which would result in significant inhalation exposure to these products;
- do not produce significant systemic toxicity by oral or dermal routes of exposure;

- do not result in inhalation exposure or inhalation toxicity based on actual human use data.

RECOMMENDATIONS: At this time, the acute inhalation waiver requests are denied. Although both products are in pellet form, the Agency is concerned about potential acute inhalation toxicity resulting from exposure to defiant particles that may be generated during packaging, shipping and handling. Due to the relatively toxic nature of brodifacoum and the potential hazard that could result from dust inhalation, the Agency requests the performance of a granular attrition study to demonstrate that the test material is non-friable. The results of this study will indicate whether the granules are likely to produce fine particles when subjected to shipping and handling. A complete and thorough description of all attrition study parameters and resulting particle size data should be included as part of the resubmission. If the granular attrition simulation indicates less than 1% of particles are smaller than 100 micrometers in size, the Agency will reconsider the waiver requests for the acute inhalation studies.

In response to the registrant's other claims, the results of the acute oral and acute dermal toxicity studies are not necessarily representative of the degree of inhalation and, therefore, are not adequate to support the waiver request for acute inhalation. Furthermore, the lack of customer calls related to inhalation exposure over the past 3 years is not indicative of a minimal inhalation risk to humans.

At this time, the waiver requests for the acute inhalation study is denied and the Agency requests that a granular attrition study be performed. However, the Agency may reconsider the waiver requests upon receipt of particle attrition data.

Date: 4/23/99

MEMORANDUM

SUBJECT: Request for review of Data Waiver(s) and/or Time Extension(s) Submitted in Response to the Product Specific DCI Issued With:

RED (name): Brodifacoum Case #: 2755

TO: Debra McCall, PRS/PCRS/TRB/RD

FROM: Venus Eagle, CRM
PRB/SRRD
Telephone # 703·308·8045

Please review the attached request(s) for data waiver(s) and/or time extension(s). Please give recommendations for approval, disapproval or other action(s) with rationale/reasons as appropriate.

EPA Product Registration #	GLN#	T W *	Approval/ Disapproval/ Other Action	EPA Product Registration #	GLN#	T W *	Approval/ Disapproval/ Other Action
[redacted]							
3282-74	81-3	W	NO				
3282-81	81-3	W	NO				

* T = Request for Time extension
W = Request for data Waiver

Ann M. Hayes 4/27/99
Reviewer's Signature Date

Request for a Waiver of the Requirement to Conduct an Acute Inhalation Study-Guideline 81-3

d-Con LIM-N8 Rat Killer in Ready-To-Use Bait Packs, EPA Reg. No. 3282-74
ID# 3282-RD-6924

Case Name: Brodifacoum
Case No.: 2755

In response to the Data Call-In Response of the Reregistration Eligibility Document (RED) for Brodifacoum, Reckitt & Colman requests that the requirement to conduct an acute inhalation toxicity study on the above D-Con rodenticide product be waived. The Agency's Interim Policy on Waiver Criteria for Inhalation Studies, a Memorandum from Penelope Fenner-Crisp, Director Health Effect Division, to Anne E. Lindsay, Director Registration Division, Policy on Acute Inhalation Toxicity Data Waivers, 12/8/91), states that "...waivers can be granted provided the Registrant adequately demonstrates that inhalation exposures will not occur under conditions of use ..." This reference also states that "Some pesticides are by their nature impossible to generate in inhalable form and thus pose no inhalation hazard. These include... non-friable granules." In addition, as stated in this reference, "Any chemical which cannot be generated as an aerosol and has a low vapor pressure is an excellent candidate for a waiver." Reference is also directed to the Acute Toxicity Waiver Guidance Document, a 1993 Memorandum from Thomas C. Ellwanger, Section head, Precautionary Review Section, Registration Division. The above references are attached.

Due to the chemical and physical characteristics of this product and the conditions of its registered use, significant inhalation exposure is not expected to occur during normal use. We believe that the following information and data demonstrate adequate support for this waiver request:

1) This product consists of solid, non-friable bait pellets which generate only a minimal amount of dust during packaging, shipping and handling. They are packaged in ready-to-use bait trays or wedges (no larger than 3 oz. or 85 g) and exposure to the end-user is minimal when opening and hand placing the packages. In the unlikely event that any dust from the D-Con pellets were to be inhaled by the end-user, the information below on both animal toxicity and human use indicate that no adverse effects would be expected.

2) The active ingredient brodifacoum cannot be generated as an aerosol because it is bound up in the solid, non-friable pellet. Brodifacoum has a low vapor pressure (9.8×10^{-7} Torr; pg. 48 EPA Rodenticide Cluster RED). Therefore, exposure to any vapor is anticipated to be negligible reducing the likelihood of inhalation exposure. Please refer to EPA memorandum on Acute Toxicity Waiver Guidance Document. In particular, the note on the bottom of page 4, "Vapor pressure levels are considered in relation to the toxicity of the material under consideration."

3) Acute toxicity studies showed that D-Con bait products containing 0.005% Brodifacoum have an Oral LD50 value of greater than 5000 mg/kg in rats and an acute dermal LD50 of greater than 2000 mg/kg in rabbits (see attached studies). We feel that the dermal LD50 is likely to be greater than 5000 mg/kg considering that the dermal LD50 of the brodifacoum formulation concentrate (0.25%), which is 50x higher than the end-use brodifacoum concentration of 0.005%, was greater than 2000 mg/kg in rats (Rodenticide cluster RED pg. 12) and no deaths were observed at 2000 mg/kg dose in rabbits in the dermal limit study with the 0.005% product. These data place the D-Con bait pellet products in EPA Category IV and demonstrate that there is little risk of systemic toxicity by exposure to this product via different routes of exposure. Based on the known data, no systemic toxicity would be expected from inhalation exposure to products containing 0.005% brodifacoum. Therefore, given the acute toxicity profile of the 0.005% brodifacoum bait pellet products, we feel that little useful information will be gained by conducting an acute inhalation toxicity study.

4) During the past (3) years, our records of customer call-ins indicate a total of (58) customer calls regarding the over 92 million units of product sold. None of these calls involved inhalation exposure related to D-Con. These data support the prediction that residential use of D-Con does not result in significant inhalation exposure and that there is minimal to no risk of inhalation toxicity to the end-user.

These data indicate that the normal handling of D-Con:

- does not generate aerosols, vapors or significant dust which would result in significant inhalation exposure to these products;

- does not produce significant systemic toxicity by oral or dermal routes of exposure;

- does not result in inhalation exposure or inhalation toxicity based on actual human use data.

Based on the above, we believe that these data are sufficient to justify a waiver of the required inhalation toxicity study. As cited in 40CFR Subsection 158.45 (a), "...the generation of acute inhalation toxicity data would not be useful in the Agency's evaluation of the risks or benefits of the product" and because further testing would needlessly use additional laboratory animals.

Attached References:

US EPA OPPTS Interim Policy on Waiver Criteria for Inhalation Studies, a Memorandum from Penelope Fenner-Crisp, Director Health Effect Division, to Anne E. Lindsay, Director Registration Division, Policy on Acute Inhalation Toxicity Data Waivers, 12/8/91.

Acute Toxicity Waiver Guidance Document, a 1993 Memorandum from Thomas C. Ellwanger, Section head, Precautionary Review Section, Registration Division.

US EPA OPPTS Reregistration Eligibility Decision (RED); Rodenticide Cluster. List B, Cases 2100, 2205, 2755, 2760, 2765, and 2810. Pgs. 12 and 48. July, 1998.

Oral Toxicity in Rats on Rodenticide U-1-86. MB Research Laboratories, Inc. Project 84-7069A. 1984.

Acute Dermal Toxicity in Albino Rabbits on Rodenticide U-1-86. MB Research Laboratories, Inc. Project 84-7069B. 1984.

DATE OUT: 15/JUNE/04

SUBJECT: PRODUCT CHEMISTRY REVIEW OF: TGAI [ ]; MUP [ ]; EUP [x]
BARCODE No.: 303912 **EPA RECEIVED DATE:** 04/12/04 **MRID Nos.:** 462395-01, 462395-02
Reg./File Symbol Nos/Product Names: 3282-65/d-CON Mouse Prufe II, 3282-66/d-CON Bait Pellets, 3282-74/d-CON Bait Pellets II, 3282-81/d-CON Ready Mixed Baitbits
COMPANY NAME: Reckitt Benckiser, Inc. **Action Code:** 675

FROM: Maria Rivera Piansay, Chemist
Product Chemistry Team
PRB/SRRD (7508C)

Accept.
PC

TO: Venus Eagle-Kunst, CRM
Product Reregistration Branch
Special Review and Reregistration Division (7508C)

INTRODUCTION:

With this resubmission, Reckitt Benckiser, Inc., provided additional product chemistry data (Storage Stability and Corrosion Characteristics) in support of the FIFRA Section 4 reregistration of EPA Reg. Nos. **3282-65** (d-CON Mouse Prufe II), **3282-66** (d-CON Bait Pellets), **3282-74** (d-CON Bait Pellets II), and **3282-81** (d-CON Ready Mixed Baitbits).

FINDINGS:

1. The product chemistry data provided in MRID numbers 462395-01 and 462395-02 are adequate and satisfy Guidelines GLNs 830-6317 and -6320 which pertain to the products' Storage Stability and Corrosion Characteristics, respectively. The study was conducted for an extended period of 2 years. Samples were stored at room temperature and were analyzed for active ingredient content at the end of the 3rd, 6th, 12th and 24th -month periods. The study was expanded to include samples stored at an elevated temperature (105°F) and analyzed for percent active ingredient after 3 months of storage. The active ingredient was determined using HPLC, with UV detection at 262 nm. Separation was achieved with an ODS column and a methanol/water/acetic acid mobile phase. The study was conducted in full compliance with the GLP standards.

   An interim report on the study was previously submitted to the Agency for review (M. Piansay, Barcode # 289656, dated 05/08/03) in which it was concluded that the method of preparing analytical samples were questionable, therefore, the laboratory utilized an alternate method of preparing the samples during the 6-month analytical interval. The Agency accepted the new method, however, the registrant was requested to submit supporting data to establish validation of the method. In this resubmission, the registrant provides a comprehensive report on the completed 2-year study (MRID number 462395-02) showing results from both the old and the new methods. Analyses on freshly made products were also conducted using the new method. Results are presented in MRID number 462395-01.

   Data Summary (MRID number 462395-02):

   Initial:

Reference #	Ave. Brodifacoum (ppm)
811-048A	49

2. The Corrosion Characteristics study was conducted in combination with the Storage Stability study. The products' packaging were evaluated for any changes such as leaking, paneling, cracking or discoloration, at each time interval (only room temperature samples were evaluated). Samples were observed for phase separation, precipitation, clumping, or discoloration. Visual observations at each time interval revealed no significant physical changes in the packaging or in the samples.

CONCLUSIONS:

The submitted Storage Stability and Corrosion Characteristics data are acceptable to support these products and the registrant has now satisfied the product chemistry data requirements for the reregistration of EPA Reg. Nos. **3282-65, 3282-66, 3282-74,** and **3282-81**.

NOTE TO CRM:

Except for the suggested blocking of the Storage and Disposal section with solid lines (which should be addressed during label review), the product chemistry aspects of the draft labeling for all four products are acceptable, as noted by P. Horng in previous reviews.

M.R. Piansay and Central File (EPA Reg. Nos. 3282-65, -66, 74, -81)
7508C:SRRD:PRB:CM-2: M.R.P.:(15/JUNE/03):703-308-8063:<3282-65, -66, 74, -81>

DATE OUT: 7/JAN/2003

SUBJECT: PRODUCT CHEMISTRY REVIEW OF Manufacturing Use Product [], End-Use Product [x] BARCODE No. : D287564 ; CASE No.: 026120 ;EPA RECEIVED DATE: 31/OCT/02 ; EPA REG./File Symbol No.: 3282-81; PRODUCT NAME: D-CON Ready Mixed Baitbits ; COMPANY NAME: Reckitt Benckiser.; MRID # : 458121-01, -02, -03, -04, and -05; Action Code: 674

FROM: Paul Horng, Ph. D., Environmental Scientist
Product Chemistry Team
Product Reregistration Branch
Special Review and Reregistration Division (7508C)
Office of Pesticide Programs
USEPA

Paul Horng

TO: Venus Eagle-Kunst, CRM
Product Reregistration Branch
Special Review and Reregistration Division (7508C)
Office of Pesticide Programs
USEPA

163-17 + 20 def.
need 12 month data
(only had 3 mo. data submitted)

will be submitted by 4/30/03
Phone message from Seem on 1.13.03.

Copy given to Seem on 1.15.03

INTRODUCTION:

The registrant, Reckitt Benckiser, Inc., submitted the product chemistry data in MRID # 458121-01, -02, -03, -04, and -05; the Confidential Statement of Formula (CSF), a basic formulation dated 25/NOV/02; and a draft label received by the Agency on 6/DEC/02; requesting for reregistration of D-CON Ready Mixed Baitbits, EPA Reg. No. 3282-81.

FINDINGS:

1. A Reregistration Eligibility Decision (RED), Cases # 2100, 2205, 2755, 2760, 2765, and 2810, was issued August 3, 1998 for the Technical Grade Active Ingredients (TGAI) chlorophacinone, diphacinone, brodifacoum, bromadiolone, and bromethalin. The Agency has completed the Reregistration Eligibility Decision and determined that these chemicals, labeled and used as specified in this Reregistration Eligilibility Decision document, will not pose unreasonable risk or adverse effects to humans or the environment. Therefore, the Agency concludes that products containing brodifacoum, bromethalin, bromadicolone, chlorophacinone, and diphacinone and its sodium salts, are eligible for reregistration. The Agency has also determined that field-bait uses containing more than 0.005% chlorophacinone and diphacinone and its sodium salt are eligible for reregistration. The Agency has also determined that all used pival and its sodium salt are ineligible for reregistration and are to remain suspended.

The generic data bases of product chemistry supporting the reregistration of brodifacoum, bromethalin, bromadicolone, chlorophacinone, and diphacinone have been determined to be substantially complete. No data gap was cited.

2(a). Except for the data gaps noted in # 2(b), the submitted data in MRID # 458121-05 satisfy the data requirements for the Guidelines 61-1 (830-1550, Product Identity and Composition), 61-2a (830-1600, Description of Materials Used to Produce the Product), 61-2b (830-1650, Description of Manufacturing Processes), 61-3 (830-1670, Discussion of Formation of Impurities), 62-3 (830-1800, Enforcement Analytical Method), 63-2 (830-6302, Color), 63-3 (830-6303, Physical State), 63-4 (830-6304, Odor), and 63-7 (830-7300, Density). The submitted Confidential Statement of Formula (CSF), a basic formulation dated 25/NOV/02, satisfy the data requirement for the Guideline 62-2 (830-1750, Certified Limits). The data requirements for the Guidelines 62-1 (830-1700, Preliminary Analysis), 63-12 (830-7000, pH), 63-14 (830-6314, Oxidizing/Reducing Action), 63-15 (830-6315, Flammability), 63-16 (830-6316, Explodability), 63-18 (830-7100, Viscosity), 63-19 (830-6319, Miscibility), and 63-21 (830-6321,

Dielectric Breakdown Voltage) are not applicable to this product and are waived.

2(b). The submitted data in MRID # 458121-02 to fulfill the data requirements for the Guideline 63-17 (830-6317, ~~Storage Stability) and 63-20 (830-6320, Corrosion Characteristics)~~, which have been stored at room temperature for 0, 3, and 6 months. The stability data indicated that the concentration of the active ingredient, brodifacoum, in the product after 3 months storage was on the border line of acceptance. The product stored at 40°C (or 105°F) for three monthes, instability of the active ingredient in the product was observed. The mean concentration was 38.25 ppm. Additional storage stability data, 12 months, are required for evaluation.

3. The submitted CSF, a basic formulation dated 25/NOV/02, has been filled out completely and correctly. The nominal concentration, upper limit, and lower limit of the active and inert ingredients in the CSF comply with the requirement of 40 CFR 158.175 (b)(2). All ingredients claimed in the CSF have been cleared for use in pesticide formulation. The CSF is acceptable.

4. Except for the storage and disposal statements must be placed in a box of solid line to increase its prominence, the active ingredient statement on the label is acceptable. The physical and chemical properties of the product indicate that there is neither physical nor chemical hazards for the product, thus, there is no such warning statement on the label is required. The Storage and Disposal statements are adequate.

CONCLUSION:

Except for the data gaps noted in the Finding # 2(b), the registrant has satisfied all product chemistry data requirements for reregistration of this product. Once the outstanding data have been submitted and satisfied, the Agency will have no objection to the reregistration of the D-CON Ready Mixed Baitbits , EPA Reg. No. 3282-81.

Group B: Series 830- Physical and Chemical Properties (40 CFR 158.190)
MRID # 458121-01.

GUIDELINE REFERENCE NO.(GRN)/TITLE 830-	VALUE OR QUALITATIVE DESCRIPTION/ METHODS USED WHERE APPLICABLE AND REFERENCES	Comments
-6302 Color.	Mottled green tint.	A
-6303 Physical State.	Solid.	A
-6304 Odor.	Wheat-like smell.	A
-6314 Oxidation/ Reduction Action.	N/A, the product contains neither oxidizing nor reducing agent.	N/A
-6315 Flammability.	N/A, the product contains no combustible liquid.	N/A
-6316 Explodability.	N/A, the product contains no explosive agents. No explosive potential is anticipated.	N/A
-6317 Storage Stability.	The test substance, formula 4-PA-165, batch B02029A , green bits or crumbles, packaged in three 12 ounce cardboard boxes, with four individual 3-ounce cardboard boxes inside each box. They have been stored at room temperature for 0, 3, and 6 months. One set of two samples stored at 40°C for three months was made. The 12 and 24 months storage and corrosion studies are on going. The mean concentrations of brodifacoum in the product after 0, 3, and 6 months of storage at room temperature were found to be at 50.5, 46.25, and 48.12 ppm, respectively, with standard deviation of 1.23,4.97, and 2.90, respectively. The product stored at 40°C for three months, the mean concentration of brodifacoum in the product was found at 38.75 ppm, with standard deviation of 4.89. MRID # 458121-05.	twelve month storage stability data are required.
-6319 Miscibility.	N/A, the product is solid and not to be diluted with water.	N/A
-6320 Corrosion Characteristics	The test substance, formula 4-PA-165, batch B02029A. green bits or crumbles, packaged in three 12 ounce cardboard boxes, with four individual 3-ounce cardboard boxes inside each box. They have been stored at room temperature for 0, 3, and 6 months. The 12 and 24 months storage and corrosion studies are on going. No corrosion on the package by the test substance was observed.	Twelve month storage stability data are required.
-7000 pH.	N/A, the product is a solid loose grain formulation.	N/A
-7100 Viscosity.	N/A, the product is not a liquid.	N/A
-7300 Bulk Density	0.62 g/ml or 39 lbs/cu. ft.	A

A: acceptable; N/A: not applicable; Gap: data gap; NR: not required.

Pages 139-141 – *Manufacturing process information may be entitled to confidential treatment*

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DATA MATRIX

Date October 9, 2006	EPA Reg No./File Symbol 3282-81	Page 1 of 3
Applicant's/Registrant's Name & Address: Reckitt Benckiser Inc Morris Corporate Center IV 399 Interpace Parkway Parsippany, NJ 07054	Product: d-Con® Ready Mix Baitbits	

Ingredient: (PC # 112701) Brodifacoum CAS# 56073-10-0

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
40 FR 158.150	PRODUCT CHEMISTRY				
830.1550	Product Identity and Composition	45812105	Reckitt Benckiser Inc	OWN	
830.1600	Description of Materials Used to Produce the Product	45812105	Reckitt Benckiser Inc	OWN	
830.1620	Description of the Production Process	45812105	Reckitt Benckiser Inc	OWN	
830.1650	Description of the Formulation Process	45812105	Reckitt Benckiser Inc	OWN	
830.1670	Discussion of Formation of Impurities	45812105	Reckitt Benckiser Inc	OWN	
830.1700	Preliminary Analysis	WAIVED	Reckitt Benckiser Inc	OWN	
830.1750	Certified Limits	See CSF	Reckitt Benckiser Inc	OWN	
830.1800	Enforcement of Analytical Method	45812105	Reckitt Benckiser Inc	OWN	
830.6302	Physical & Chemical Characteristics - Color	45812105	Reckitt Benckiser Inc	OWN	
830.6303	Physical & Chemical Characteristics - Physical State	45812105	Reckitt Benckiser Inc	OWN	
830.6304	Physical & Chemical Characteristics - Odor	45812105	Reckitt Benckiser Inc	OWN	
830.6314	Physical & Chemical Characteristics – Oxidizing / Reducing	WAIVED	Reckitt Benckiser Inc	OWN	

Signature	Name and Title:	Date
Liane Jenkins	Liane Jenkins, Regulatory Specialist	10/9/06

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Ingredient: (PC # 112701) Brodifacoum CAS# 56073-10-0

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
40 CFR 158.150	PRODUCT CHEMISTRY cont.				
830.6315	Physical & Chemical Characteristics – Flammability	WAIVED	Reckitt Benckiser Inc	OWN	
830.6316	Physical & Chemical Characteristics – Explodability	WAIVED	Reckitt Benckiser Inc	OWN	
830.6317	Physical & Chemical Characteristics – Storage & Stability	45812102 46239502	Reckitt Benckiser Inc	OWN	
830.6319	Physical & Chemical Characteristics – Miscibility	WAIVED	Reckitt Benckiser Inc	OWN	
830.6320	Physical & Chemical Characteristics - Corrosion	45812102 46239502	Reckitt Benckiser Inc	OWN	
830.6321	Physical & Chemical Characteristics – Dielectric breakdown voltage	WAIVED	Reckitt Benckiser Inc	OWN	
830.7000	Physical & Chemical Characteristics - pH	WAIVED	Reckitt Benckiser Inc	OWN	
830.7100	Physical & Chemical Characteristics - Viscosity	WAIVED	Reckitt Benckiser Inc	OWN	
830.7300	Physical & Chemical Characteristics - Density	45812105	Reckitt Benckiser Inc	OWN	
40 CFR 160.105	Uniformity Evaluation	45812103	Reckitt Benckiser Inc		
40 CFR 158.340	TOXICOLOGY				
870.1100	Acute Oral Toxicity- Rats	44983701	Syngenta, Greensboro, NC 27419-8300	CITE	
870.1200	Acute Dermal Toxicity - Rabbits	45718901	Hacco Inc., Madison, WI 53716	CITE	

Signature	Name and Title:	Date
Liane Jenkins	Liane Jenkins, Regulatory Specialist	10/9/06

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Ingredient: (PC # 112701) Brodifacoum CAS# 56073-10-0		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
40 CFR 158.340	TOXICOLOGY cont.				
870.1300	Acute Inhalation Toxicity - Rats	45760701	Syngenta, Greensboro, NC 27419-8300	CITE	
870.2400	Acute Eye Irritation - Rabbit	44597901	Syngenta, Greensboro, NC 27419-8300	CITE	
870.2500	Acute Dermal Irritation - Rabbits	44021703	Syngenta, Greensboro, NC 27419-8300	CITE	
870.2600	Skin Sensitization: Local Nymph Node Assay	44021704	Syngenta, Greensboro, NC 27419-8300	CITE	
40 CFR	PRODUCT PERFORMANCE				
96-10	Commensal Rodenticide Efficacy	456309-01	Syngenta, Greensboro, NC 27419-8300	CITE	
96-10	Commensal Rodenticide Efficacy	456525-01	Syngenta, Greensboro, NC 27419-8300	CITE	
96-10	Commensal Rodenticide Efficacy	45248501	Syngenta, Greensboro, NC 27419-8300	CITE	
96-10	Commensal Rodenticide Efficacy	45248502	Syngenta, Greensboro, NC 27419-8300	CITE	
96-10	Commensal Rodenticide Efficacy	45248503	Syngenta, Greensboro, NC 27419-8300	CITE	
96-10	Commensal Rodenticide Efficacy	45248504	Syngenta, Greensboro, NC 27419-8300	CITE	
96-10	Commensal Rodenticide Efficacy	45020501	Syngenta, Greensboro, NC 27419-8300	CITE	
96-10	Commensal Rodenticide Efficacy	45020502	Syngenta, Greensboro, NC 27419-8300	CITE	
96-10	Commensal Rodenticide Efficacy	45020503	Syngenta, Greensboro, NC 27419-8300	CITE	
96-10	Commensal Rodenticide Efficacy	45020504	Syngenta, Greensboro, NC 27419-8300	CITE	

Signature	Name and Title:	Date
Liane Jenkins	Liane Jenkins, Regulatory Specialist	10/9/06

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Ingredient: (PC # 112701) Brodifacoum CAS# 56073-10-0

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]	[redacted]	[redacted]			
			Reckitt Benckiser Inc	OWN	
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			Reckitt Benckiser Inc	OWN	

Signature	Name and Title:	Date
Liane Jenkins	Liane Jenkins, Regulatory Specialist	10/9/06

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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]	[redacted]	[redacted]			
			Reckitt Benckiser Inc	OWN	
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			Reckitt Benckiser Inc	OWN	
			Reckitt Benckiser Inc	OWN	
			Reckitt Benckiser Inc	OWN	
			Reckitt Benckiser Inc		
			Syngenta, Greensboro, NC 27419-8300	CITE	
			Hacco Inc., Madison, WI 53716	CITE	

Signature	Name and Title:	Date
Liane Jenkins	Liane Jenkins, Regulatory Specialist	10/9/06

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Ingredient: (PC # 112701) Brodifacoum CAS# 56073-10-0		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]	[redacted]	[redacted]			
			Syngenta, Greensboro, NC 27419-8300	CITE	
			Syngenta, Greensboro, NC 27419-8300	CITE	
			Syngenta, Greensboro, NC 27419-8300	CITE	
			Syngenta, Greensboro, NC 27419-8300	CITE	
			Syngenta, Greensboro, NC 27419-8300	CITE	
			Syngenta, Greensboro, NC 27419-8300	CITE	
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			Syngenta, Greensboro, NC 27419-8300	CITE	
			Syngenta, Greensboro, NC 27419-8300	CITE	
			Syngenta, Greensboro, NC 27419-8300	CITE	

Signature	Name and Title:	Date
	Liane Jenkins, Regulatory Specialist	10/9/06

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DATA MATRIX

Date November 25, 2002	EPA Reg No./File Symbol 3282-81	Page 1 of 4
Applicant's/Registrant's Name & Address Reckitt Benckiser Inc., 1655 Valley Road, Wayne New Jersey 07474	Product d-CON Ready Mixed Baitbits	

Ingredient Brodifacoum

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Product Chemistry				
830.1000	Product Properties Test Guidlines	New	Reckitt Benckiser Inc.	Own	
830.1550	Product Identity and Composition	New	Reckitt Benckiser Inc.	Own	
830.1600	Description of Materials Used to Produce the Product	New	Reckitt Benckiser Inc.	Own	
830.1620	Descritpion of the Production Process	New	Reckitt Benckiser Inc.	Own	
830.1650	Descritption of the Formulation Process	New	Reckitt Benckiser Inc.	Own	
830.1670	Discussion of Formation of zimpurities	New	Reckitt Benckiser Inc.	Own	
830.1700	Preliminary Analysis	New	Reckitt Benckiser Inc.	Own	
830.1750	Certified Limits	New	Reckitt Benckiser Inc.	Own	
830.1800	Enforcement method	New	Reckitt Benckiser Inc.	Own	
830.1900	Submittal of Samples	New	Reckitt Benckiser Inc.	Own	
830.6302	Color	New	Reckitt Benckiser Inc.	Own	
830.6303	Physical State	New	Reckitt Benckiser Inc.	Own	
830.6304	Odor	New	Reckitt Benckiser Inc.	Own	
830.6314	Oxidation/Reduction	New	Reckitt Benckiser Inc	Own	

Signature	Name and Title	Date
Sean McNear	Sean McNear, Sr. Regulatory Affairs Specialist	11/25/02

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Applicant's/Registrant's Name & Address Reckitt Benckiser Inc., 1655 Valley Road, Wayne New Jersey 07474	Product d-CON Ready Mixed Baitbits	

Ingredient Brodifacoum

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]	[redacted]	[redacted]			
			Reckitt Benckiser Inc.	Own	
			Reckitt Benckiser Inc.	Own	
			Reckitt Benckiser Inc.	Own	
			Reckitt Benckiser Inc.	Own	
			Reckitt Benckiser Inc.	Own	
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			Reckitt Benckiser Inc.	Own	
			Reckitt Benckiser Inc.	Own	
			Reckitt Benckiser Inc.	Own	
			Reckitt Benckiser Inc	Own	

Signature Sean McNear	Name and Title Sean McNear, Sr. Regulatory Affairs Specialist	Date 11/25/02

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Ingredient Brodifacoum

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Product Chemistry				
830.6315	Flammability	New	Reckitt Benckiser Inc.	Own	
830.6316	Explodability	New	Reckitt Benckiser Inc.	Own	
830.6317	Storage Stability	New	Reckitt Benckiser Inc.	Own	
830.6319	Miscibility	New	Reckitt Benckiser Inc.	Own	
830.6320	Corrosion Characteristics	New	Reckitt Benckiser Inc.	Own	
830.6321	Dielectric Breakdown	New	Reckitt Benckiser Inc.	Own	
830.7000	pH	New	Reckitt Benckiser Inc.	Own	
830.7100	Viscosity	New	Reckitt Benckiser Inc.	Own	
830.7300	Density/Relative Density/Bulk Density	New	Reckitt Benckiser Inc.	Own	
40 CFR 160.105	Uniformity Evaluation	New	Reckitt Benckiser Inc.	Own	

Signature	Name and Title	Date
Sean McNear	Sean McNear, Sr. Regulatory Affairs Specialist	11/25/02

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 204660

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspects of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date	EPA Reg No./File Symbol	Page
November 25, 2002	3282-81	2 of 4

Applicant's/Registrant's Name & Address
Reckitt Benckiser Inc., 1655 Valley Road, Wayne New Jersey 07474

Product
d-CON Ready Mixed Baitbits

Ingredient Brodifacoum

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]	[redacted]	[redacted]			
			Reckitt Benckiser Inc.	Own	
			Reckitt Benckiser Inc.	Own	
			Reckitt Benckiser Inc.	Own	
			Reckitt Benckiser Inc.	Own	
			Reckitt Benckiser Inc.	Own	
			Reckitt Benckiser Inc.	Own	
			Reckitt Benckiser Inc.	Own	
			Reckitt Benckiser Inc.	Own	
			Reckitt Benckiser Inc.	Own	
			Reckitt Benckiser Inc.	Own	

Signature Sean McNear

Name and Title
Sean McNear, Sr. Regulatory Affairs Specialist

Date 11/25/02

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
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DATA MATRIX

Date	EPA Reg No./File Symbol	Page
November 25, 2002	3282-81	3 of 4

Applicant's/Registrant's Name & Address	Product
Reckitt Benckiser Inc., 1655 Valley Road, Wayne New Jersey 07474	d-CON Ready Mixed Baitbits

Ingredient: Brodifacoum

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]	[redacted]	[redacted]			
			Syngenta, Greensboro, NC 27419-8300	PER	
			Hacco Inc., Madison, WI 53716	PER	
			Syngenta, Greensboro, NC 27419-8300	PER	Attrition/Trans.
			Syngenta, Greensboro, NC 27419-8300	PER	
			Syngenta, Greensboro, NC 27419-8300	PER	
			Syngenta, Greensboro, NC 27419-8300	PER	

Signature	Name and Title	Date
Sean McNear	Sean McNear, Sr. Regulatory Affairs Specialist	11/25/02

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Public File Copy

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 204660

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspects of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date November 25, 2002	EPA Reg No./File Symbol 3282-81	Page 3 of 4
Applicant's/Registrant's Name & Address Reckitt Benckiser Inc., 1655 Valley Road, Wayne New Jersey 07474	Product d-CON Ready Mixed Baitbits	

Ingredient Brodifacoum

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Toxicology				
81-1	Acute Oral LD-50 (rat)	44983701	Syngenta, Greensboro, NC 27419-8300	PER	
81-2	Acute Dermal LD-50	45718901	Hacco Inc., Madison, WI 53716	PER	
81-3	Acute Inhalation LC-50 (rat)	New	Syngenta, Greensboro, NC 27419-8300	PER	Attrition/Trans.
81-4	Primary Eye Irritation (rabbit)	44597901	Syngenta, Greensboro, NC 27419-8300	PER	
81-5	Primary Dermal Irritation	44021703	Syngenta, Greensboro, NC 27419-8300	PER	
81-6	Dermal Sensitization	44021704	Syngenta, Greensboro, NC 27419-8300	PER	

Signature Sean McNear	Name and Title Sean McNear, Sr. Regulatory Affairs Specialist	Date 11/25/02

458121-00

RECKITT BENCKISER

November 26, 2002

Document Processing Desk (**RED-SRRD-PRB**)
Office of Pesticide Programs (7504C)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Hwy.
Arlington, VA 22202

RE: Documentation to Support Reregistration of the Following Products:
d-CON Mouse Prufe II (3282-65)
d-CON Bait Pellets (3282-66)
d-CON Bait Pellets II (3282-74)
d-CON Ready Mixed Baitbits (3282-81)

To whom it may concern,

Please find the documentation to support the reregistration of the products listed above. All four products have the same formulation (4-PA-165). All four products share the same efficacy reports and the product chemistry reports. The toxicity reports are cited as identified in the attached data matrix.

Reckitt Benckiser is requesting two name changes for the following registrations. Registration 3282-66 is currently identified as d-CON Pellets Generation II. The new name for registration 3282-66 is **d-CON Bait Pellets**. The registration 3282-81 is currently identified as d-CON Ready Mixed Generation II. The new name for registration 3282-81 is **d-CON Ready Mixed Baitbits**.

All of the appropriate documentation is included in the data packages. Please refer to the transmittal document for the complete list of information. Please call me with any questions at 973-686-7390. Thank you in advance for your assistance.

Sincerely,

Sean McNear
Sr. Regulatory Affairs Specialist

RECKITT BENCKISER INC.
1655 Valley Road, P.O. Box 943, Wayne, NJ 07474-0943
T[redacted]973)-633-3600 FAX: (973)-633-3633

Product Name: d-CON Mouse Prufe II

EPA File Symbol 3282-65

TRANSMITTAL DOCUMENT

1. Name and address of submitter:

Reckitt Benckiser Inc.
1655 Valley Road
Wayne, NJ 07474

2. Regulatory action in support of which this package is submitted:

Application for Reregistration

3. Transmittal date:

November 25, 2002

4. Vol. 1 Administrative materials

A) Cover letter
B) Application for Pesticide (EPA Form 8570-1)
C) Confidential Statement of Formula
D) Certification with Respect to Citation of Data
E) Manufacturing Procedure (see Product Chemistry Report)
F) Data Matrix
G) Five copies of Draft Label
H) Letters of Authorization

5 Vol. 2 Product Chemistry

45812101 A) 1. Product Chemistry of Formula 4-PA-165
Data Requirements OPPTS 830.1000
Study Number 2002-0102

45812102 B) 2. Product Stability 830.6317 Storage Stability; 830.6320 Corrosion Characteristics 40 CFR 160.135
Study Number 2002-0044

45812103 C) 3. Product Chemistry, Uniformity Evaluation of Formula 4-PA-165
Study Number 2002-0068

45812104 D) 4. Product Chemistry, Uniformity Evaluation of Formula 4-PA-165
Study Number 2002-0063

45812105 E) 5. Product Properties (Group A and B) for Formula 4-PA-165

6. Vol. 3 Efficacy Studies

A) Final Report (3 copies)

45812106 6. Determining the Efficacy of Anticoagulant Dry Bait Rodenticide Using Feed Choice Test with Albino Laboratory Rats (Wistar Rats), Test Method 1.203, Including Explanation Document
Study Number: 13760.4109

45812107 B) Final Report (3 copies)
7. Determining the Efficacy of Anticoagulant Dry Bait Rodenticide Using Feed Choice Test with Albino Laboratory Rats (Wistar Rats), Test Method 1.203, Including Explanation Document
Study Number: 13760.4102

45812108 C) Final Report (3 copies)
8. Determining the Efficacy of Anticoagulant Dry Bait Rodenticide Using Feed Choice Test with the House Mouse, Test Method 1.204, Including Explanation Document
Study Number: 13760.4108

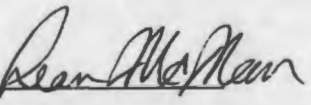
45812109 D) Final Report (3 copies)
9. Determining the Efficacy of Anticoagulant Dry Bait Rodenticide Using Feed Choice Test with the Albino Laboratory Mice (*Mus musculis*, CD-1), Test Method 1.204, Including Explanation Document
Study Number: 13760.4101

45812110 E) Final Report (3 copies)
10. Norway Rat (*Rattus norvegicus*) Acute Dry Bait Laboratory, Test Method 1.209: One day Test
Study Number: 01024

45812111 F) Final Report (3 copies)
11. House Mouse (*Mus musculus*) Acute Dry Bait Laboratory, Test Method 1.210: One day Test
Study Number: 00040

45812112 G) Final Report (3 copies)
12. The Efficacy of Anticoagulant Dry Bait Rodenticide Using a Place-Pack Penetration Test with Albino Laboratory Rats (Wistar Rats), Test Method 1.217
Study Number: 13760.4103

45812113 H) Final Report (3 copies)
13. The Efficacy of Anticoagulant Dry Bait Rodenticide Using a Place-Pack Penetration Test with Albino Laboratory Mice (*Mus musculus, CD-1*), Test Method 1.218
Study Number: 13760.4104

Company Official: Sean McNear 

Company Name: Reckitt Benckiser Inc.

Company Contact: Sean McNear (973) 686-7390

syngenta

Rich Lotstein
Regulatory Team Leader
Regulatory Affairs
rich.lotstein@syngenta.com
(336) 632-7442

Syngenta Crop Protection, Inc.
P. O. Box 18300
410 Swing Road
Greensboro, NC 27419-8300

November 6, 2002

Ms. Venus Eagle
SRRD (H7508C)
Office of Pesticide Programs (H7504C)
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Crystal Mall 2 – Room 266A
Arlington, VA 22202

Subject: Reckitt-Benckiser
EPA Registration Numbers 3282-65, -66, -74, and -81
Active Ingredient: Brodifacoum
Authorization to Reference Syngenta's Data

Dear Ms. Eagle:

Syngenta Crop Protection, Inc. hereby authorizes the U.S. Environmental Protection Agency to refer to the following Syngenta study, as of the date of this letter only, to support the FIFRA registration eligibility decision (RED) concerning the subject products of Reckitt-Benckiser:

Kaukeinen, D.E.; Ashton, D.; Jackson, W.B.; et al. (1980) Efficacy to Warfarin-Resistant House Mice : MRID Number 00042578

This authorization is qualified to the extent, however, that: (1) the applicant or any other person, except your Agency shall not have access to said data unless specifically authorized in writing by Syngenta, or when in the opinion of your Agency it is required in judicial administrative proceedings; (2) this authorization shall not be construed as authorization to use or consider said data, directly or indirectly, in support of any subsequent application submitted by the applicant; and (3) this authorization shall not be transferred by the applicant in any manner whatsoever without express prior consent of Syngenta (4) this authorization may be withdrawn by Syngenta at any time; and (5) this authorization shall be null and void if the applicant amends its registration to include any source of the subject active ingredient other than Syngenta Crop Protection, Inc.

Sincerely,

Rich Lotstein
Regulatory Affairs

cc: Sean McNear Sean.McNear@reckittbenckiser.com

S. Cosky,
D. Meier
J. Hott
T. Brodie
J. Pauley
Customer Service File – Reckitt & Benckiser

October 29, 2002

Ms. Venus Eagle-Kunst
SRRD (H7508C)
Office of Pesticide Programs (H7504C)
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Crystal Mall 2 – Room 266A
Arlington, VA 22202

Subject: Reckitt & Benckiser
EPA Registration Numbers 3282-65, -66, -74, and -81
Active Ingredient: Brodifacoum
Authorization to Reference Syngenta's Data

Dear Ms. Eagle-Kunst:

Syngenta Crop Protection, Inc. hereby authorizes the U.S. Environmental Protection Agency to refer to the following Syngenta studies for the active ingredient brodifacoum, as of the date of this letter only, to support the FIFRA registration eligibility decision (RED) concerning the subject products of Reckitt & Benckiser.

Studies	MRID Numbers
Acute Oral	44983701
Acute inhalation	Syngenta recently sent attrition & transportation study to EPA
Acute eye irritation	44597901
Acute dermal irritation	44021703
Skin sensitization	44021704

This authorization is qualified to the extent, however, that: (1) the applicant or any other person except your Agency shall not have access to said data unless specifically authorized in writing by Syngenta, or when in the opinion of your Agency it is required in judicial administrative proceedings; (2) this authorization shall not be construed as authorization to use or consider said data, directly or indirectly, in support of any subsequent application submitted by the applicant; and (3) this authorization shall not be transferred by the applicant in any manner whatsoever without express prior consent of Syngenta (4) this authorization may be withdrawn by Syngenta at any time; and (5) this authorization shall be null and void if the applicant amends its registration to include any source of the subject active ingredient other than Syngenta Crop Protection, Inc.

Sincerely,

Trina Brodie
Regulatory Assistant

cc: Sean McNear Sean.McNear@reckittbenckiser.com

Bcc: S. Cosky,
D. Meier
J. Hott
R. Lotstein
J. Pauley
Customer Service File – Reckitt & Benckiser

Syngenta Crop Protection, Inc. Tel 336 632 6000
P.O. Box 18300
Greensboro, NC 27419-8300
www.syngenta.com

syngenta

October 5, 2006

Ms. Julia Stokes
SRRD (7508P) – 9th Floor
Office of Pesticide Programs
U.S. Environmental Protection Agency
One Potomac Yards
2777 South Crystal Drive – Room S-4900
Arlington, VA 22202

Subject: **Reckitt & Benckiser**
EPA Registration Numbers 3282-65, -66, -74, and -81
Active Ingredient: Brodifacoum
Authorization to Reference Syngenta's Data

Dear Ms. Stokes:

Syngenta Crop Protection, Inc. hereby authorizes the U.S. Environmental Protection Agency to refer to the following Syngenta efficacy studies for the active ingredient brodifacoum, as of the date of this letter only, to support the registration application concerning the subject products of Reckitt & Benckiser.

MRID Numbers

456309-01
456525-01
452485-01
452485-02
452485-03
452485-04
450205-01
450205-02
450205-03
450205-04

This authorization is qualified to the extent, however, that: (1) the applicant or any other person except your Agency shall not have access to said data unless specifically authorized in writing by Syngenta, or when in the opinion of your Agency it is required in judicial administrative proceedings; (2) this authorization shall not be construed as authorization to use or consider said data, directly or indirectly, in support of any subsequent application submitted by the applicant; and (3) this authorization shall not be transferred by the applicant in any manner whatsoever without express prior consent of Syngenta (4) this authorization may be withdrawn by Syngenta at any time; and (5) this

syngenta

authorization shall be null and void if the applicant amends its registration to include any source of the subject active ingredient other than Syngenta Crop Protection, Inc.

Sincerely,

Trina Brodie

Trina Brodie
Regulatory Specialist

cc: Liane Jenkins – liane.jenkins@reckittbenckiser.com

HACCO, INC.

Rec'd 8-23-02

Manufacturing Plant
110 Hopkins Drive
Randolph, WI 53956-1316
(920) 326-5141
FAX (920) 326-5135

Registration Office
P.O. Box 7190 (53707)
5900 Monona Dr.
Water Tower Place, Suite 200
Madison, WI 53716
(608) 221-6200 • FAX (608) 221-7380

August 19, 2002

Document Processing Desk
Office of Pesticide Programs (7504-C)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202
ATTN: Venus Eagle

Airborne
8718811496

Subject: Submission of Product Specific Data Required in the Call-Ins in Connection to the Reregistration Eligibility Documents (REDs) of August 10, 1998 with Revised Correspondence dated March 14, 2002
Brodifacoum, Case No. 2755, Chemical No. 12710

Dear Ms. Eagle:

In response to a recent request from our supplier, Syngenta Crop Protection, Inc., we are hereby authorizing the use of the following study to support the 0.005% end-use brodifacoum products held by Reckitt Benckiser:

Acute Dermal Limit Study, IRI Study #146.010 -- MRID #45718901

We hereby authorize the use of this study for our supplier, Syngenta, Inc.'s customer Reckitt Benckiser. This information is to be considered proprietary, supplied by HACCO, Inc. and should not be released to Reckitt Benckiser.

If you should have any questions in this matter, please call me at 608/221-7378.

Sincerely,

Judith A. Thompson

Judith A. Thompson
Registration Manager
Rodenticides

Enclosure

cc: Scott Baker
John Hott/Syngenta
Lee Schwalenberg
Jeannie Smith

c:\word\judy\reg ltr - epa & misc\acute derm stdy auth for Reckitt Benskiser.IT.sp

459184-00

RECKITT BENCKISER

April 16, 2003

Document Processing Desk (**RED-SRRD-PRB**)
Office of Pesticide Programs (7504C)
~~Room 266A, Crystal~~ Mall 2
1921 Jefferson Davis Hwy.
Arlington, VA 22202
Venus Eagle

RE: Documentation to Support Reregistration of the Following Products:
d-CON Mouse Prufe II (3282-65)
d-CON Bait Pellets (3282-66)
d-CON Bait Pellets II (3282-74)
d-CON Ready Mixed Baitbits (3282-81)

Dear Venus,

Please find the documentation to support the reregistration of the products listed above. All four products have the same formulation (4-PA-165). All four products share the same stability report attached. The stability report is ongoing for the full two years, however we are providing the 1 year analysis. Please find enclosed data for the above registration:

1. EPA Application number 289021
2. 3 copies of the 1 year stability report of formula 4-PA-165 45918401

Please call me with any questions at 973-686-7390. Thank you in advance for your assistance.

Sincerely,

Sean McNear
Sr. Regulatory Affairs Specialist

RECKITT BENCKISER INC.
1655 Valley Road, P.O. Box 943, Wayne, NJ 07474-0943
Tel. (973) 633-3600 • Fax (973) 633-3633

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

JUN 22 1999

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

CERTIFIED MAIL -BF-02
Mr. Bob Fellows
Reckitt & Colman Inc.
1800 Valley Road
P.O. Box 942
Wayne, New Jersey 07474-0942

Subject: Brodifacoum Acute Inhalation Waiver Requests
EPA Reg. No. 3282-74 and 3282-81

Dear Mr. Fellows:

In response to the Reregistration Eligibility Decision (RED) for the Rodenticide Cluster, the Agency has reviewed your (90 day response) request for acute inhalation toxicity waivers. The acute inhalation wavier requests for EPA Reg. Nos. 3282-74 and 3282-81 have been denied. Although both products are in pellet form, the Agency is concerned about the potential acute inhalation toxicity resulting from exposure to defiant particles that may be generated during packaging, shipping and handling. However, a granular attrition study may be conducted to demonstrate that the test material is non-friable. If the granular attrition simulation indicates less than 1% of the particles are smaller than 100 micrometers in size, the Agency will reconsider the waiver requests for the acute inhalation studies. See the enclosed Agency review dated 4/27/99 for further specifics. Should Recitt & Colman choose to pursue the waiver request, the attrition study must be submitted within 60 days from receipt of this letter. Otherwise the Agency will expect acute inhalation toxicity studies for EPA Reg. Nos. 3282-74 and 3282-81 on or before September 30, 1999.

The Agency is providing you with the time frames mentioned to adequately address the deficiencies noted in the Agency's April 27, 1999 review. Failure to adequately respond within those time frames may result in a Notice of Intent to Suspend affecting the registration of your Brodifacoum products. A copy of the Agency's review dated 4/27/99 is enclosed for your records. If you have any questions, please contact Venus Eagle at (703) 308-8045.

Sincerely,

Linda S. Propst, Chief
Product Reregistration Branch
Special Review and
Reregistration Division

CONCURRENCES

SYMBOL	7508C	7508C						
Enclosure SURNAME	V. Eagle	Propst						
DATE	6-21-99	6/22/99						

RECKITT BENCKISER

FAX

Regulatory Affairs
1655 Valley Road
Wayne, NJ 07474

Tele: 973 686-7390
Fax: 973 686-7396

No. Pages including this cover page: 14

TO: Venus Eagle

DATE:

COMPANY: EPA

FROM: Sean McNear

FAX: 703 - 605 - 0656

SUBJECT: UPDated Data Call-In Response for RED

Please find requested Information
Thank you again for your assistance.

Regards,

Sean McNear

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

11 SEP 1997

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Dear Registrant:

Your request for a change in your Official EPA Company Name and Address of record has been completed. For your confirmation a copy of the printed screen from the company name and address database is enclosed. This address of record should be your mailing address.

Any future changes in company name and/or address or changes in designation/withdrawal of authorized agent should be directed to the following address. It can be mailed or faxed to (703) 305-7670.

Document Processing Desk (COADR)
Office of Pesticide Programs - 7504C
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington D.C. 20460-0001

If you have any questions regarding your EPA company name and address of record, please call me on (703) 305-5361.

Sincerely,

Maureen Sherrill

Maureen Sherrill
Information Management Specialist
Office of Pesticide Programs

Company Data Report

Company No.: 777

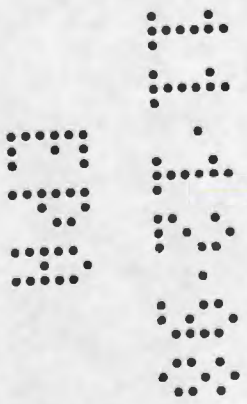
Name: HOUSEHOLD PRODUCTS DIVISION, RECKITT & COLMAN INC
ATTN: REGULATORY AFFAIRS DEPARTMENT

Address: 1655 VALLEY ROAD
WAYNE, NJ 07470
USA

Contact: EILEEN MOYER Phone: (201) 573-6314

Agent: N
Consortium: N
Undeliverable: N

Company Types	Active Flag



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

March 14, 2002

(Registrant Name)

Subject: Revised Due Dates for Submission of Product-Specific and Generic Data Required in Data Call-Ins Issued in Connection with the Rodenticide Cluster and Zinc Phosphide Reregistration Eligibility Documents (REDs)

Dear (registrant),

The Agency previously issued Product-Specific Data Call-Ins (PDCI) and Generic Data Call-Ins (GDCI) in connection with the Rodenticide Cluster and Zinc Phosphide REDs. These DCIs were issued in December and August 1998, respectively. As a long-term risk reduction measure listed in the Rodenticide Cluster RED, the Agency formed the Rodenticide Stakeholder Workgroup (RSW) and formally convened five times over an eight month period in 1999 to discuss means of significantly reducing exposures to children and pets. Due to the RSW process, all data requirements were temporarily put on hold. The signing of the rodenticide Federal Register Notice (FRN) on November 13, 2001, and its recent publication on November 28th, 2001, have now resolved the issues which originally held-up initiation of the time frames for submission of the data required by the1998 DCIs.

Therefore, this letter is to inform registrants that the date of your receipt of this letter will begin the time frames for data submission as required per the Rodenticide and Zinc Phosphide PDCIs and GDCIs.

Revised Data Call-In Response and Requirements Status and Registrant's Response forms are required for Rodenticide Cluster and Zinc Phosphide products labeled for use to control certain mammal pests **within 30 days** of your receipt of this letter. Product-Specific Data are required to be submitted to the Agency or cited within 8 months of your receipt of this letter. Generic data are due within the time frames specified in the GDCIs. Previously submitted Generic and Product Specific Data Call-In Response and Requirements Status and Registrant's Response forms are no longer applicable. All registrants are required to submit new forms which have been enclosed. Registrants that have previously submitted data voluntarily may cite those studies when responding to the Requirements Status and Registrant's Response form.

Please use the following mailing addresses for all rodenticide correspondence and data submissions sent to OPP by U.S. mail:

A. U.S. Postal Service Deliveries

1. Generic Reregistration Responses

Document Processing Desk
Office of Pesticide Programs (7504-C)
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Ave., NW
Washington, D.C. 20460-0001

ATTN: John Pates

2. Product Specific Reregistration Responses

Document Processing Desk
Office of Pesticide Programs (7504-C)
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Ave., NW
Washington, D.C. 20460-0001

ATTN: Venus Eagle [for Brodifacoum, Bromadiolone, Bromethalin, and Chlorophacinone,]

or

ATTN: Frank Rubis [for Zinc Phosphide or Diphacinone]

Or use the following addresses for all rodenticide correspondence and data submissions that are hand-carried or sent by courier service Monday through Friday, from 8:00 AM to 4:30 PM, excluding Federal holidays:

B. Personal/Courier Service Deliveries

1. Generic Reregistration Responses

Document Processing Desk
Office of Pesticide Programs (7504-C)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, Virginia 22202

ATTN: John Pates

2. Product Specific Reregistration Responses

Document Processing Desk
Office of Pesticide Programs (7504-C)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, Virginia 22202

ATTN: Venus Eagle [for Brodifacoum, Bromadiolone, Bromethalin, and Chlorophacinone.]

or

ATTN: Frank Rubis [for Zinc Phosphide or Diphacinone]

Failure to adequately respond within 30 days from receipt of this letter and submit the required data within the time frames specified in the DCI's and PDCI's may result in a Notice of Intent to Suspend affecting the registrations of your rodenticide product(s). If you have any questions regarding the generic data please contact *John Pates at 703-308-8195* or for product specific questions, please contact *Venus Eagle at 703-308-8045.*

Sincerely,

Lois A. Rossi, Director
Special Review and
Reregistration Division

Attachments: 1. Data Call-In Response Form, and Requirement Status and Registrant's Response Form
2. Product Specific Data Call-In Response Form, and Product Specific Requirement Status and Registrant's Response Form

United States Environmental Protection Agency
Washington, D. C. 20460

DATA CALL-IN RESPONSE

Form Approved

OMB No. 2070-0107
2070-0057

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company name and Address	2. Case # and Name	3. Date and Type of DCI
RECKITT BENCKISER INC. 1655 VALLEY ROAD WAYNE NJ 07474	2755 Brodifacoum	PRODUCT SPECIFIC

4. EPA Product Registration	5. I wish to cancel this product registration voluntarily.	6. Generic Data		7. Product Specific Data	
		6a. I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA registration number listed below.	6b. I agree to satisfy Generic Data requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response."	7a. My product is a MUP and I agree to satisfy the MUP requirements on the attached form entitled "Requirements Status and Registrant's Response."	7b. My product is an EUP and I agree to satisfy the EUP requirements on the attached form entitled "Requirements Status and Registrant's Response."
3282-81		N.A.	N.A.		Yes

8. Certification

I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.

Signature and Title of Company's Authorized Representative: Sean McNear Sr. Regulatory Affairs Specialist

9. Date: April 23, 2002

10. Name of Company Contact: Sean McNear

11. Phone Number: 973-686-7390

United States Environmental Protection Agency
Washington, D. C. 20460

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

Form Approved
OMB No. 2070-0107
2070-0057

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company name and Address	2. Case # and Name	3. Date and Type of DCI
RECKITT BENCKISER INC. 1655 VALLEY ROAD WAYNE NJ 07474	2755 Brodifacoum EPA Reg. No. 3282-81	PRODUCT SPECIFIC ID# 3282-RD-6926

4. Guideline Requirement Number	5. Study Title	PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
	Prod Chem - Regular Chemical								
830.1550	Product identity & composition (1)					K M O	MP/EP	8 mos.	1
830.1600	Description of materials used (1,2) to produce the product					K M O	MP/EP	8 mos.	1
830.1670	Discussion of formation of (1,3) impurities					K M O	MP	8 mos.	1
830.1700	Preliminary analysis (1,4)					K M O	MP	8 mos.	1
830.1750	Certified limits (1,5)					K M O	MP/EP	8 mos.	1
830.1800	Enforcement analytical method (1)					K M O	MP/EP	8 mos.	1
830.6302	Color (17)					K M O	MP/EP	8 mos.	1
830.6303	Physical state					K M O	MP/EP	8 mos.	1
830.6304	Odor (17)					K M O	MP/EP	8 mos.	1
830.7300	Density					K M O	MP/EP	8 mos.	1
	(9)					K M O	MP/EP	8 mos.	
830.6317	Storage stability (18)					K M O	MP/EP	8 mos.	1
830.6320	Corrosion characteristics					K M O	MP/EP	8 mos.	1

10. Certification

I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.

Signature and Title of Company's Authorized Representative: Sean McNear Sr. Regulatory Affairs Specialist

11. Date: April 23, 2002

12. Name of Company Contact: Sean McNear

13. Phone Number: 973-686-7390

United States Environmental Protection Agency
Washington, D. C. 20460

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

Form Approved
OMB No. 2070-0107
2070-0057

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company name and Address	2. Case # and Name	3. Date and Type of DCI
RECKITT BENCKISER INC. 1655 VALLEY ROAD WAYNE NJ 07474	2755 Brodifacoum EPA Reg. No. 3282-81	PRODUCT SPECIFIC ID# 3282-RD-6926

4. Guideline Requirement Number	5. Study Title		PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
	Acute toxic - Regular Chemical									
870.1100	Acute oral toxicity	(1,50)					K M O	MP/EP	8 mos.	X 2
870.1200	Acute dermal toxicity	(1,2,50)					K M O	MP/EP	8 mos.	X 2
870.1300	Acute inhalation toxicity	(3,50)					K M O	MP/EP	8 mos.	X 2
870.2400	Acute eye irritation	(2,50)					K M O	MP/EP	8 mos.	X 2
870.2500	Acute dermal irritation	(1,2,50)					K M O	MP/EP	8 mos.	X 2
870.2600	Skin sensitization	(4,50)					K M O	MP/EP	8 mos.	X 2
	Efficacy - Vertebrate Control Agents									
96-10	Commensal rodenticides	(50)					K M O	EP	8 mos.	1

H43

20.92.10

Initial to indicate certification as to information on this page (full text of certification is on page one). SM

Date: April 23, 2002

United States Environmental Protection Agency
Washington, D. C. 20460

FOOTNOTES AND KEY DEFINITIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 2755 Brodifacoum

Key: MP = manufacturing-use product; EP = end-use product; provided formulators purchase their active ingredient(s) from a registered source, they need not submit or cite data pertaining to the purchased product. [NOTE: If a product is a 100 percent repackage of another registered product, registrants are not subject to any data requirements identified in the tables.]; TEP = typical end-use product; TGAI = technical grade of the active ingredient; PAI = "pure" active ingredient; PAIRA = "pure" active ingredient, radiolabeled.

Use Categories Key:

A - Terrestrial food crop	B - Terrestrial food-feed crop	C - Terrestrial nonfood crop	D - Aquatic food crop	E - Aquatic nonfood outdoor
F - Aquatic nonfood Industrial	G - Aquatic nonfood residential	H - Greenhouse food crop	I - Greenhouse nonfood crop	J - Forestry
K - Residential outdoor	L - Indoor food	M - Indoor nonfood	N - Indoor Medical	O - Indoor residential

Footnotes: [The following notes are referenced in column two (5. Study Title) of the REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE form.]

Prod Chem - Regular Chemical

1 Requirements pertaining to product identity, composition, analysis, and certification of ingredients are detailed further in the following sections: *158.155 for product identity and composition (61-1); *158.160, 158.162, and 158.165 for description of starting materials and manufacturing process (61-2); *158.167 for discussion of formation of impurities (61-3); *158.170 for preliminary analysis (62-1); *158.175 for certification of limits (62-2); and *158.180 for enforcement analytical methods (62-3).

2 A schematic diagram and/or brief description of the production process will suffice if the pesticide is not already under full scale production and an experimental use permit is being sought.

3 If the pesticide is not already under full scale production and an experimental use permit is sought, a discussion of unintentional ingredients shall be submitted to the extent this information is available.

4 To support registration of an MP or EP, whether produced by an integrated system or not, the technical grade of Active Ingredient must be analyzed. If the technical grade of Active Ingredient cannot be isolated, a statement of composition of the practical equivalent of the technical grade of Active Ingredient must be submitted. Data on EPs or MPs will be required on a case-by-case basis.

5 Certified limits are not required for inert ingredients in products proposed for experimental use.

9 Required if test substances are dispersible with water.

17 Not required unless efficacy data are required.

18 Required for MP and EP but should not be submitted for EP unless (a) efficacy data are required to be submitted, (b) the storage stability data show that the active ingredient(s) is (are) not within the certified limits or toxicologically significant degradates are detected, or (c) product instability is suspected or incidents of instability are reported. Refer to PR Notice 92-5 for more information.

Acute Toxic - Regular Chemical

1 Not required if test material is a gas or highly volatile.

2 Not required if test material is corrosive to skin or has pH less than 2 or greater than 11.5; such a product will be classified as Toxicity Category I on the basis of potential eye and dermal irritation effects.

3 Required if the product consists of, or under conditions of use will result in, an inhalable material (e. g., gas, volatile substances, or aerosol/particulate).

4 Required unless repeated dermal exposure does not occur under conditions of use.

50 Acute Toxicity Footnote 50 for Brodifacoum, Bromadialone, Diphacinone and its Sodium Salt, Chlorophacinone, Bromethalin, and Zinc Phosphide.

The Agency requires data to support each manufacturing and end-use product.

United States Environmental Protection Agency
Washington, D. C. 20460

FOOTNOTES AND KEY DEFINITIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 2755 Brodifacoum

Footnotes (cont.):

For a manufacturing-use product, a registrant may satisfy this requirement in three ways:

1) submit data on actual product
2) cite data on actual product
3) cite data on product in same batch

For an end-use product, a registrant may satisfy this requirement in five ways:

1) submit data on actual product
2) cite data on actual product
3) cite data on product in same batch
4) cite data on any product having the same % active and source, provided both products contain 95% food grade materials and the remaining inerts would not be expected to change the toxicity category.
5) cite data on the non-technical source material concentrate, provided end-use product contains 95% food grade materials and the remaining inerts would not be expected to change the toxicity category. For example, data for the 0.25% Brodifacoum Concentrate would support most 0.005% Brodifacoum end-use formulations.

Efficacy - Vertebrate Control Agents

50 Efficacy Data Footnote 50 for Brodifacoum, Bromadiolone, Diphecinone and its Sodium Salt, Chlorophacinone, Bromethalin, and Zinc Phosphide.

Efficacy data must be submitted or cited to support claims for rodents that may directly or indirectly transmit diseases to humans. In the past, registrants have established the efficacy for most, but not all, claims. To continue any public health claims on current labels, registrants need the following types of data to be on file with the Agency:

PUBLIC HEALTH USES		TYPE OF DATA
Sites	Pests	NEEDED
ALL	Norway Rat, Roof Rat,	Laboratory
	House Mice	Laboratory
ALL	Prairie Dogs	Laboratory & Field
ALL	Ground Squirrels	Laboratory & Field
ALL	Peromyscus spp.	Laboratory & Field

United States Environmental Protection Agency
Washington, D. C. 20460

FOOTNOTES AND KEY DEFINITIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 2755 Brodifacoum

Footnotes (cont.):

All laboratory efficacy studies must be run with the specific bait formulation that is in the product being supported.

The Agency requires the following laboratory (OPP Designations) and field tests, depending on the pesticide and species of pest:

I. ANTICOAGULANTS

FORMULATION	SPECIES	GUIDELINE NO (OPP DESIGNATION)	EXPOSURE PERIOD
Solid Baits (non-wax)	Norway/Roof Rat	96-10	
		1.203 or	15
		1.209	1
[If bait is in placepack, add:		1.217	15 or 1]
	House Mouse	96-10	
		1.204 or	15
		1.210	1
[If bait is in placepack, add:		1.218	15 or 1]
	Ground Squirrels	96-12	
	Prairie Dogs	96-12	
Solid Baits (Wax Blocks & Pellets)	Norway/Roof Rats	96-10	
		1.213 or	15
		1.209	1
	House Mouse	96-10	
		1.214 or	15
		1.210	1
	Ground Squirrels	96-12	
	Prairie Dogs	96-12	
Liquid Baits	Norway/Roof Rat	96-10	15
		1.201	
	House Mouse	96-10	15
		1.202	
Tracking Powder	Norway/Roof Rat	96-10	15
		1.205	

United States Environmental Protection Agency
Washington, D. C. 20460

FOOTNOTES AND KEY DEFINITIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 2755 Brodifacoum

Footnotes (cont.):

	House Mouse	96-10 1.212	15
Concentrate/ Technical	Norway Rat	96-10 1.221	
	House Mouse	96-10 1.225	
	Peromyscus spp. (deer mice, white-footed mice, etc.)	96-12 or 96-11 1.216 1.223	

If no "single-feeding" claim is made, the bait-exposure period is 15 days. If a "single-feeding" claim is desired, the exposure period is 1 day.

II. NON-ANTICOAGULANTS
(Bromethalin and Zinc Phosphide)

Solid Baits	Norway/Roof Rat	96-10 1.209	2 or 1
[If bait is in placepack, add:		1.219	2 or 1
	House Mouse	96-10 1.210	2 or 1
[If bait is in placepack, add:		1.220	2 or 1
	Ground Squirrels	96-12	
	Prairie Dogs	96-12	
Tracking Powder	Norway/Roof Rat	96-10 1.211	2 or 1
	House Mouse	96-10 1.227	2 or 1
Concentrate/ Technical	Norway Rat	96-10 1.222	
	House Mouse	96-10 1.226	

United States Environmental Protection Agency
Washington, D. C. 20460

FOOTNOTES AND KEY DEFINITIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 2755 Brodifacoum

Footnotes (cont.):

Peromyscus spp. (deer mice, white-footed mice, etc.)	96-12 or 96-11 1.215 1.224

If no "single-feeding" claim is made, the exposure is 2 days. If a "single-feeding" claim is desired, the exposure period is 1 day.

Applicability of 3-Day Tests:

If claims have been accepted previously (prior to issuance of this RED) based upon results of trials with 3-day bait exposure periods, no new efficacy data may be needed, PROVIDED that the bait formulation does not change and that single-feeding claims are deleted from all labeling.

General Comments about all Placepacks:

Efficacy requirements for placepacks include a choice-feeding test (e.g., 1.203) plus a placepack-penetration test (e.g., 1.217).

General Comments about Ready-to-Use Bait Stations:

Efficacy requirements for ready-to-use bait stations are similar to those for placepacks, but protocols 1.217 and 1.218, etc., must be adapted to accomodate the specific product design being tested. Protocols should be reviewed and accepted by EPA before tests are initiated. SAFETY TESTS ALSO ARE REQUIRED IF READY-TO-USE STATIONS ARE CLAIMED TO BE "TAMPER-RESISTANT".

Questions about Tests:

If you have questions about these tests, call Dr. William Jacobs at 703-305-6406.

How to Satisfy Requirements:

You may satisfy the data requirements in two ways:

1. Submit or Cite (provide MRID or Accession No.) data
2. Repack Another Registered Product

Cite the the product that is repacked. Submit or cite NO data. The sites and pests claimed for your product may not extend beyond those claimed for the repacked product.

Southeastern Solutions, Inc.

2862 Ft. McAllister Road
P.O. Box 2147
Richmond Hill, GA 31324
Phone (912)727-3525 Fax (912) 727-2580

April 25, 2002

Beverly Stroud
Document Processing Desk (NEWCO)
Office of Pesticide Programs (7504C)
U. S. Environmental Protection Agency
Ariel Rio Building
1200 Pennsylvania Avenue, NW
Washington, DC 20460

FAX 703-305-7670

Dear Ms. Stroud:

Southeastern Solutions, Inc. is requesting an EPA Company Number.

Please forward the necessary paperwork to:

SOUTHEASTERN SOLUTIONS, INC.
P. O. Box 2147
Richmond Hill, GA 31324

Your Prompt attention to this matter is most appreciated.

Sincerely,

Harry R. Ford, Jr.

HRFjr:vaw

The Divisions of Southeastern Solutions, Inc.

912•727•3525
912•727•2531
2862 Ft. McAllister Rd.
Richmond Hill, GA 31324

Fax 912•727•2580
Hgtrs 368 1170
E-mail Seasolinc@worldnet att net

Office E-mail:vwhf@msn.com

TOTAL PAGES 2

FAX NUMBER: 1-703-305-7670

FAX TO: Document Processing Desk (NEWCO)

ATTEN: Beverly Stroud

MESSAGE: Requesting EPA Company Number
See letter p.2 Please 1-912-727-2580
if you need additional information

FROM: Virginia Woodcock
for Harry Ford

Harry Ford III
President

Harry Ford Jr.
Regional Sales

SOUTHEASTERN
SOLUTIONS AND SESOLINC MILITARY SHELTERS

United States Environmental Protection Agency
Washington, D. C. 20460

DATA CALL-IN RESPONSE

Form Approved
OMB No. 2070-0107
2070-0057

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company name and Address	2. Case # and Name	3. Date and Type of DCI
RECKITT BENCKISER INC. 1655 VALLEY ROAD WAYNE NJ 07474	2755 Brodifacoum	PRODUCT SPECIFIC

4. EPA Product Registration	5. I wish to cancel this product registration voluntarily.	6. Generic Data		7. Product Specific Data	
		6a. I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA registration number listed below.	6b. I agree to satisfy Generic Data requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response."	7a. My product is a MUP and I agree to satisfy the MUP requirements on the attached form entitled "Requirements Status and Registrant's Response."	7b. My product is an EUP and I agree to satisfy the EUP requirements on the attached form entitled "Requirements Status and Registrant's Response."
3282-81		N.A.	N.A.		Yes

8. Certification

I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.

Signature and Title of Company's Authorized Representative: Sean McNear Sr. Regulatory Affairs Specialist

9. Date: April 23, 2002

10. Name of Company Contact: Sean McNear

11. Phone Number: 973-686-7390

United States Environmental Protection Agency
Washington, D. C. 20460

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

Form Approved
OMB No. 2070-0107
2070-0057

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RECKITT BENCKISER INC. 1655 VALLEY ROAD WAYNE NJ - 07474	2755 Brodifacoum EPA Reg. No. 3282-81	PRODUCT SPECIFIC ID# 3282-RD-6926

4. Guideline Requirement Number	5. Study Title		PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
	Prod Chem - Regular Chemical									
830.1550	Product identity & composition	(1)					K M O	MP/EP	8 mos.	1
830.1600	Description of materials used to produce the product	(1,2)					K M O	MP/EP	8 mos.	1
830.1670	Discussion of formation of impurities	(1,3)					K M O	MP	8 mos.	1
830.1700	Preliminary analysis	(1,4)					K M O	MP	8 mos.	1
830.1750	Certified limits	(1,5)					K M O	MP/EP	8 mos.	1
830.1800	Enforcement analytical method	(1)					K M O	MP/EP	8 mos.	1
830.6302	Color	(17)					K M O	MP/EP	8 mos.	1
830.6303	Physical state						K M O	MP/EP	8 mos.	1
830.6304	Odor	(17)					K M O	MP/EP	8 mos.	1
830.7300	Density						K M O	MP/EP	8 mos.	1
		(9)					K M O	MP/EP	8 mos.	
830.6317	Storage stability	(18)					K M O	MP/EP	8 mos.	1
830.6320	Corrosion characteristics						K M O	MP/EP	8 mos.	1

10. Certification

I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.

Signature and Title of Company's Authorized Representative: Sean McNear Sr. Regulatory Affairs Specialist

11. Date: April 23, 2002

12. Name of Company Contact: Sean McNear

13. Phone Number: 973-686-7390

United States Environmental Protection Agency
Washington, D. C. 20460

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

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OMB No. 2070-0107
2070-0057

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4. Guideline Requirement Number	5. Study Title		PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
	Acute Toxic - Regular Chemical									
870.1100	Acute oral toxicity	(1,50)					44923701 K M O	MP/EP	8 mos.	~~K~~ 6
870.1200	Acute dermal toxicity	(1,2,50)					45718901 K M O	MP/EP	8 mos.	~~K~~ 6
870.1300	Acute inhalation toxicity	(3,50)	Protocol Study				Waived K M O	MP/EP	8 mos.	~~K~~ 6
870.2400	Acute eye irritation	(2,50)					44597901 K M O	MP/EP	8 mos.	~~K~~ 6
870.2500	Acute dermal irritation	(1,2,50)					44021703 K M O	MP/EP	8 mos.	~~K~~ 6
870.2600	Skin sensitization	(4,50)					44021704 K M O	MP/EP	8 mos.	~~K~~ 6
	Efficacy - Vertebrate Control Agents									
96-10	Commensal rodenticides	(50)					K M O	EP	8 mos.	1

Initial to indicate certification as to information on this page (full text of certification is on page one). SM

Date: April 23, 2002

RECKITT & COLMAN

November 9, 1998

Document Processing Desk (**RED-SRRD-PRB**)
Office of Pesticide Programs (7504C)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Hwy.
Arlington, VA 22202

Reference: Case Name: Brodifacoum
Case No. 2755
ID No. 3282-RD-6926

d-CON Ready Mixed Generation II, EPA Reg. No. 3282-81

Dear Sir or Madam:

Enclosed is the 90 day Data Call In response form from Reckitt & Colman Inc. for the above registration. As required for this response, a data waiver for Acute inhalation is being requested and is provided.

As noted on the Requirements Status and Registrant's Response form, we will be submitting new studies for all other data requirements.

Our address has been corrected, and a copy of the previous notification to the agency is enclosed. Should you require further information regarding this submission, please contact me.

Sincerely,

Bob Fellows

Bob Fellows
Regulatory Affairs
Tel: 973/686-7389
Fax: 973/686-7396
EMail: Bob.Fellows@Reckitt.com

United States Environmental Protection Agency
Washington, D. C. 20460

DATA CALL-IN RESPONSE

Form Approved
OMB No. 2070-0107
2070-0057
Approval Expires 03-31-99

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company name and Address	2. Case # and Name	3. Date and Type of DCI
RECKITT & COLMAN INC, HOUSEHOLD PROD ATTN: EPA REGULATORY DEPT ~~225 SUMMITT AVE~~ 1655 Valley Road ~~MONTVALE NJ 07645~~ Wayne, NJ 07470	2755 Brodifacoum	PRODUCT SPECIFIC

4. EPA Product Registration	5. I wish to cancel this product registration voluntarily.	6. Generic Data		7. Product Specific Data	
		6a. I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA registration number listed below.	6b. I agree to satisfy Generic Data requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response."	7a. My product is a MUP and I agree to satisfy the MUP requirements on the attached form entitled "Requirements Status and Registrant's Response."	7b. My product is an EUP and I agree to satisfy the EUP requirements on the attached form entitled "Requirements Status and Registrant's Response."
3282-81		N.A.	N.A.		YES

8. Certification

I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.

Signature and Title of Company's Authorized Representative Bob Fellows Regulatory Affairs

9. Date: November 9, 1998

10. Name of Company Contact: Bob Fellows

11. Phone Number: 973/686-7389

United States Environmental Protection Agency
Washington, D. C. 20460

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

Form Approved
OMB No. 2070-0107
2070-0057
Approval Expires 03-31-99

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company name and Address
RECKITT & COLMAN INC, HOUSEHOLD PROD
ATTN: EPA REGULATORY DEPT
~~225 SUMMITT AVE~~ 1655 Valley Road
MONTVALE NJ 07645 Wayne, NJ 07470

2. Case # and Name
2755 Brodifacoum

EPA Reg. No. 3282-81

3. Date and Type of DCI
PRODUCT SPECIFIC
ID# 3282-RD-6926

4. Guideline Requirement Number	5. Study Title		PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
	Prod Chem - Regular Chemical									
61-1	Product identity & composition	(1)					K M O	MP/EP	8 mos.	1
61-2(a)	Descriptn starting materials, productn & formulatn process	(1,2)					K M O	MP/EP	8 mos.	1
61-2(b)	Discussion of formation of impurities	(1,3)					K M O	MP	8 mos.	1
62-1	Preliminary analysis	(1,4)					K M O	MP	8 mos.	1
62-2	Certification of limits	(1,5)					K M O	MP/EP	8 mos.	1
62-3	Analytical method	(1)					K M O	MP/EP	8 mos.	1
63-2	Color	(17)					K M O	MP/EP	8 mos.	1
63-3	Physical state						K M O	MP/EP	8 mos.	1
63-4	Odor	(17)					K M O	MP/EP	8 mos.	1
63-7	Density						K M O	MP/EP	8 mos.	1
63-12	pH	(9)					K M O	MP/EP	8 mos.	1
63-17	Storage stability	(18)					K M O	MP/EP	8 mos.	1

10. Certification
I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.
Signature and Title of Company's Authorized Representative Bob Fellows Regulatory Affairs

11. Date
November 9, 1998

12. Name of Company Contact
Bob Fellows

13. Phone Number
973/686-7389

United States Environmental Protection Agency
Washington, D. C. 20460

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

Form Approved
OMB No. 2070-0107
2070-0057
Approval Expires 03-31-99

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company name and Address
RECKITT & COLMAN INC, HOUSEHOLD PROD
ATTN: EPA REGULATORY DEPT
~~225 SUMMITT AVE~~ 1655 Valley Road
~~MONTVALE NJ 07645~~ Wayne, NJ 07470

2. Case # and Name
2755 Brodifacoum

EPA Reg. No. 3282-81

3. Date and Type of DCI
PRODUCT SPECIFIC
ID# 3282-RD-6926

4. Guideline Requirement Number	5. Study Title		PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
63-20	Corrosion characteristics						K M O	MP/EP	8 mos.	1
	Acute Toxic - Regular Chemical									
81-1	Acute oral toxicity-rat	(1,50)					K M O	MP/EP	8 mos.	1
81-2	Acute dermal toxicity-rabbit/rat	(1,2,50)					K M O	MP/EP	8 mos.	1
81-3	Acute inhalation toxicity-rat	(3,50)					K M O	MP/EP	8 mos.	7
81-4	Primary eye irritation-rabbit	(2,50)					K M O	MP/EP	8 mos.	1
81-5	Primary dermal irritation	(1,2,50)					K M O	MP/EP	8 mos.	1
81-6	Dermal sensitization	(4,50)					K M O	MP/EP	8 mos.	1
	Efficacy - Vertebrate Control Agents									
96-10	Commensal rodenticides	(50)					K M O	EP	8 mos.	1

Initial to indicate certification as to information on this page (full text of certification is on page one). BT.

Date Nov. 9, 1998

United States Environmental Protection Agency
Washington, D. C. 20460

FOOTNOTES AND KEY DEFINITIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 2755 Brodifacoum

Key: MP = manufacturing-use product; EP = end-use product; provided formulators purchase their active ingredient(s) from a registered source, they need not submit or cite data pertaining to the purchased product. [NOTE: If a product is a 100 percent repackage of another registered product, registrants are not subject to any data requirements identified in the tables.]; TEP = typical end-use product; TGAI = technical grade of the active ingredient; PAI = "pure" active ingredient; PAIRA = "pure" active ingredient, radiolabeled.

Use Categories Key:

A - Terrestrial food crop	B - Terrestrial food feed crop	C - Terrestrial nonfood crop	D - Aquatic food crop	E - Aquatic nonfood outdoor
F - Aquatic nonfood Industrial	G - Aquatic nonfood residential	H - Greenhouse food crop	I - Greenhouse nonfood crop	J - Forestry
K - Residential outdoor	L - Indoor food	M - Indoor nonfood	N - Indoor Medical	O - Indoor residential

Footnotes: [The following notes are referenced in column two (5. Study Title) of the REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE form.]

Prod Chem - Regular Chemical

1 Requirements pertaining to product identity, composition, analysis, and certification of ingredients are detailed further in the following sections: *158.155 for product identity and composition (61-1); *158.160, 158.162, and 158.165 for description of starting materials and manufacturing process (61-2); *158.167 for discussion of formation of impurities (61-3); *158.170 for preliminary analysis (62-1); *158.175 for certification of limits (62-2); and *158.180 for enforcement analytical methods (62-3).
2 A schematic diagram and/or brief description of the production process will suffice if the pesticide is not already under full scale production and an experimental use permit is being sought.
3 If the pesticide is not already under full scale production and an experimental use permit is sought, a discussion of unintentional ingredients shall be submitted to the extent this information is available.
4 To support registration of an MP or EP, whether produced by an integrated system or not, the technical grade of Active Ingredient must be analyzed. If the technical grade of Active Ingredient cannot be isolated, a statement of composition of the practical equivalent of the technical grade of Active Ingredient must be submitted. Data on EPs or MPs will be required on a case-by-case basis.
5 Certified limits are not required for inert ingredients in products proposed for experimental use.
9 Required if test substances are dispersible with water.
17 Not required unless efficacy data are required.
18 Required for MP and EP but should not be submitted for EP unless (a) efficacy data are required to be submitted, (b) the storage stability data show that the active ingredient(s) is (are) not within the certified limits or toxicologically significant degradates are detected, or (c) product instability is suspected or incidents of instability are reported. Refer to PR Notice 92-5 for more information.

Acute Toxic - Regular Chemical

1 Not required if test material is a gas or highly volatile.
2 Not required if test material is corrosive to skin or has pH less than 2 or greater than 11.5; such a product will be classified as Toxicity Category I on the basis of potential eye and dermal irritation effects.
3 Required if the product consists of, or under conditions of use will result in, an inhalable material (e. g., gas, volatile substances, or aerosol/particulate).
4 Required unless repeated dermal exposure does not occur under conditions of use.
50 Acute Toxicity Footnote 50 for Brodifacoum, Bromadialone, Diphacinone and its Sodium Salt, Chlorophacinone, Bromethalin, and Zinc Phosphide.
-
The Agency requires data to support each manufacturing and end-use product.

United States Environmental Protection Agency
Washington, D. C. 20460

FOOTNOTES AND KEY DEFINITIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 2755 Brodifacoum

Footnotes (cont.):

-

For a manufacturing-use product, a registrant may satisfy this requirement in three ways:

-

1) submit data on actual product
2) cite data on actual product
3) cite data on product in same batch

-

For an end-use product, a registrant may satisfy this requirement in five ways:

-

1) submit data on actual product
2) cite data on actual product
3) cite data on product in same batch
4) cite data on any product having the same % active and source, provided both products contain 95% food grade materials and the remaining inerts would not be expected to change the toxicity category.
5) cite data on the non-technical source material concentrate, provided end-use product contains 95% food grade materials and the remaining inerts would not be expected to change the toxicity category. For example, data for the 0.25% Brodifacoum Concentrate would support most 0.005% Brodifacoum end-use formulations.

Efficacy - Vertebrate Control Agents

50 Efficacy Data Footnote 50 for Brodifacoum, Bromadiolone, Diphacinone and its Sodium Salt, Chlorophacinone, Bromethalin, and Zinc Phosphide.

-

-

Efficacy data must be submitted or cited to support claims for rodents that may directly or indirectly transmit diseases to humans. In the past, registrants have established the efficacy for most, but not all, claims. To continue any public health claims on current labels, registrants need the following types of data to be on file with the Agency:

-

PUBLIC HEALTH USES		TYPE OF DATA
Sites	Pests	NEEDED
ALL	Norway Rat, Roof Rat,	Laboratory
	House Mice	Laboratory
ALL	Praire Dogs	Laboratory & Field
ALL	Ground Squirrels	Laboratory & Field
ALL	Peromyscus spp.	Laboratory & Field

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United States Environmental Protection Agency
Washington, D. C. 20460

FOOTNOTES AND KEY DEFINITIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 2755 Brodifacoum

Footnotes (cont.):

All laboratory efficacy studies must be run with the specific bait formulation that is in the product being supported.

The Agency requires the following laboratory (OPP Designations) and field tests, depending on the pesticide and species of pest:

I. ANTICOAGULANTS

FORMULATION	SPECIES	GUIDELINE NO (OPP DESIGNATION)	EXPOSURE PERIOD
Solid Baits (non-wax)	Norway/Roof Rat	96-10 1.203 or 1.209	 15 1
[If bait is in placepack, add:		1.217	15 or 1]
	House Mouse	96-10 1.204 or 1.210	 15 1
[If bait is in placepack, add:		1.218	15 or 1]
	Ground Squirrels	96-12	
	Prairie Dogs	96-12	
Solid Baits (Wax Blocks & Pellets)	Norway/Roof Rats	96-10 1.213 or 1.209	 15 1
	House Mouse	96-10 1.214 or 1.210	 15 1
	Ground Squirrels	96-12	
	Prairie Dogs	96-12	
Liquid Baits	Norway/Roof Rat	96-10 1.201	15
	House Mouse	96-10 1.202	15
Tracking Powder	Norway/Roof Rat	96-10 1.205	15

United States Environmental Protection Agency
Washington, D. C. 20460

FOOTNOTES AND KEY DEFINITIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 2755 Brodifacoum

Footnotes (cont.):

	House Mouse	96-10 1.212	15
Concentrate/ Technical	Norway Rat	96-10 1.221	
	House Mouse	96-10 1.225	
	Peromyscus spp. (deer mice, white-footed mice, etc.)	96-12 or 96-11 1.216 1.223	

If no "single-feeding" claim is made, the bait-exposure period is 15 days. If a "single-feeding" claim is desired, the exposure period is 1 day.

II. NON-ANTICOAGULANTS
(Bromethalin and Zinc Phosphide)

Solid Baits	Norway/Roof Rat	96-10 1.209	2 or 1
[If bait is in placepack, add:		1.219	2 or 1
	House Mouse	96-10 1.210	2 or 1
[If bait is in placepack, add:		1.220	2 or 1
	Ground Squirrels	96-12	
	Prairie Dogs	96-12	
Tracking Powder	Norway/Roof Rat	96-10 1.211	2 or 1
	House Mouse	96-10 1.227	2 or 1
Concentrate/ Technical	Norway Rat	96-10 1.222	
	House Mouse	96-10 1.226	

United States Environmental Protection Agency
Washington, D. C. 20460

FOOTNOTES AND KEY DEFINITIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 2755 Brodifacoum

Footnotes (cont.):

-

Peromyscus spp. (deer mice, white-footed mice, etc.)	96-12 or 96-11 1.215 1.224

-

If no "single-feeding" claim is made, the exposure is 2 days. If a "single-feeding" claim is desired, the exposure period is 1 day.

-

-

Applicability of 3-Day Tests:

-

If claims have been accepted previously (prior to issuance of this RED) based upon results of trials with 3-day bait exposure periods, no new efficacy data may be needed, PROVIDED that the bait formulation does not change and that single-feeding claims are deleted from all labeling.

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General Comments about all Placepacks:

-

Efficacy requirements for placepacks include a choice-feeding test (e.g., 1.203) plus a placepack-penetration test (e.g., 1.217).

-

-

General Comments about Ready-to-Use Bait Stations:

-

Efficacy requirements for ready-to-use bait stations are similar to those for placepacks, but protocols 1.217 and 1.218, etc., must be adapted to accomodate the specific product design being tested. Protocols should be reviewed and accepted by EPA before tests are initiated. SAFETY TESTS ALSO ARE REQUIRED IF READY-TO-USE STATIONS ARE CLAIMED TO BE "TAMPER-RESISTANT".

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Questions about Tests:

-

If you have questions about these tests, call Dr. William Jacobs at 703-305-6406.

-

-

How to Satisfy Requirements:

-

You may satisfy the data requirements in two ways:

-

1. Submit or Cite (provide MRID or Accession No.) data
2. Repack Another Registered Product

-

Cite the the product that is repacked. Submit or cite NO data. The sites and pests claimed for your product may not extend beyond those claimed for the repacked product.

United States Environmental Protection Agency
Washington, D. C. 20460

LIST OF ALL REGISTRANTS SENT THIS DATA CALL-IN NOTICE

Case # and Name: 2755 Brodifacoum

Co. Nr.	Company Name	Additional Name	Address	City & State	Zip
003282	RECKITT & COLMAN INC, HOUSEHOLD PR	ATTN: EPA REGULATORY DEPT	225 SUMMITT AVE	MONTVALE NJ	07645
010182	ZENECA AG PRODUCTS		BOX 15458	WILMINGTON DE	19850
011715	SPEER PRODUCTS INC		BOX 18993	MEMPHIS TN	38181
061282	HACCO, INC.		537 ATLAS AVE	MADISON WI	53716

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number	EPA Registration Number/File Symbol
Reckitt Benckiser Inc.,1655 Valley Road, Wayne,NJ 973-686-7390	3282-81
Active Ingredient(s) and/or representative test compound(s): Brodifacoum	Date: April 23, 2002
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158): Household/Indoor	Product Name: d-CON Ready Mixed Generation II

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

[XX] I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

[ ] I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

[XX] I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

[ ] I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses .

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (I) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature	Date	Typed or Printed Name and Title
Sean McNear	4/23/02	Sean McNear Sr. Regulatory Affairs Specialist

EPA Form 8570-34 (9-97) Electronic and Paper versions available. Submit only Paper version.

Please read instructions on reverse before completing form. Form Approved, OMB No. 2070-0060, Approval expires 05-31-98

EPA United States **Environmental Protection Agency** Washington, DC 20460

☐ **Registration** ☐ **Amendment** ☒ **Other**

OPP Identifier Number: 289188

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
3282-81	**Venus Eagle**	☒ None ☐ Restricted
4. Company/Product (Name) **d-CON Ready Mixed Baitbits**	PM#	

5. Name and Address of Applicant *(Include ZIP Code)*
Reckitt Benckiser Inc.
1655 Valley Road
Wayne, New Jersey 07474

☐ *Check if this is a new address*

6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(I), my product is similar or identical in composition and labeling to:
EPA Reg. No. _____
Product Name _____

Section - II

☐ Amendment - Explain below.
☐ Resubmission in response to Agency letter dated _____
☐ Notification - Explain below.
☐ Final printed labels in response to Agency letter dated _____
☐ "Me Too" Application
☒ Other - Explain below

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)
Application for Reregistration

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes* ☒ No	☒ Yes ☐ No	☐ Yes ☒ No	☐ Metal ☐ Plastic ☐ Glass ☒ Paper ☐ Other (Specify)
***Certification must be submitted**	If "Yes" Unit Packaging wgt. **3.0 oz** / No. per container **4**	If "Yes" Package wgt. / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☐ Label ☒ Container	**12 oz**	☒ On Label ☐ On labeling accompanying product

6. Manner in Which Label is Affixed to Product ☐ Lithograph ☐ Paper glued ☐ Stenciled ☒ Other **Print on carton**

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application)*

Name	Title	Telephone No. (Include Area Code)
Sean McNear	**Sr. Regulatory Affairs Specialist**	**973-686-7390**

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature	3. Title	6. Date Application Received (Stamped)
Sean McNear	**Sr. Regulatory Affairs Specialist**	
4. Typed Name **Sean McNear**	5. Date **November 25, 2002**	

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete — White- EPA File Copy (original) Yellow- Applicant Copy

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060

EPA

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☐ Other

OPP Identifier Number
289188

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification ☐ None ☐ Restricted
4. Company/Product (Name)	PM#	

5. Name and Address of Applicant *(Include ZIP Code)*

☐ *Check if this is a new address*

6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

☐ Amendment - Explain below.
☐ Resubmission in response to Agency letter dated _____
☐ Notification - Explain below.
☐ Final printed labels in response to Agency letter dated _____
☐ "Me Too" Application.
☐ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes* ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☐ Other (Specify) _____
* *Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☐ Label ☐ Container		☐ On Label ☐ On Labeling accompanying product

6. Manner in Which Label is Affixed to Product ☐ Lithograph ☐ Paper glued ☐ Stenciled ☐ Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title
4. Typed Name	5. Date

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

Please read instructions on reverse before completing form.

Form Approved, OMB No. 2070-0060, Approval expires 05-31-98

EPA	United States Environmental Protection Agency Washington, DC 20460	☐ Registration ☐ Amendment ☒ Other	OPP Identifier Number 289021

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
3282-65, 3282-66, 3282-74, 3282-81	**Venus Eagle**	☒ None ☐ Restricted
4. Company/Product (Name) **d-CON Mouse Prufe II, Bait Pellets, Bait Pellets II, Ready Mixed Baitbits**	PM#	
5. Name and Address of Applicant *(Include ZIP Code)* **Reckitt Benckiser Inc. 1655 Valley Road Wayne, New Jersey 07474** ☐ *Check if this is a new address*	6. **Expedited Review**. In accordance with FIFRA Section 3(c)(3)(b)(I), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

☐ Amendment - Explain below.
☐ Resubmission in response to Agency letter dated _____
☐ Notification - Explain below.
☐ Final printed labels in response to Agency letter dated _____
☐ "Me Too" Application
☒ Other - Explain below

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)
Additional Information for Reregistration

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes* ☒ No	☒ Yes ☐ No	☐ Yes ☒ No	☐ Metal ☐ Plastic ☐ Glass ☒ Paper ☐ Other (Specifiy)
***Certification must be submitted**	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt. / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☐ Label ☒ Container		☒ On Label ☐ On labeling accompanying product

6. Manner in Which Label is Affixed to Product ☐ Lithograph ☐ Paper glued ☐ Stenciled ☒ Other Print on carton

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application)*

Name	Title	Telephone No. (Include Area Code)
Sean McNear	**Sr. Regulatory Affairs Specialist**	**973-686-7390**

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature	3. Title	6. Date Application Received (Stamped)
Sean McNear	**Sr. Regulatory Affairs Specialist**	
4. Typed Name **Sean McNear**	5. Date **April 16, 2003**	

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete **White- EPA File Copy (original) Yellow- Applicant Copy**

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060

EPA

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☐ Other

OPP Identifier Number
289021

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
4. Company/Product (Name)	PM#	☐ None ☐ Restricted

5. Name and Address of Applicant *(Include ZIP Code)*

☐ *Check if this is a new address*

6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

☐ Amendment - Explain below.
☐ Resubmission in response to Agency letter dated _____
☐ Notification - Explain below.
☐ Final printed labels in response to Agency letter dated _____
☐ "Me Too" Application.
☐ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes* ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☐ Other (Specify) _____
* *Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☐ Label ☐ Container		☐ On Label ☐ On Labeling accompanying product

6. Manner in Which Label is Affixed to Product ☐ Lithograph ☐ Paper glued ☐ Stenciled ☐ Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title
4. Typed Name	5. Date

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Reckitt Benckiser, Inc. Morris Corporate Center IV 399 Interpace Parkway Parsippany, NJ 07054	EPA Registration Number/File Symbol 3282-81
Active Ingredient(s) and/or representative test compound(s) Brodifacoum	Date October 9, 2006
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Rodenticide	Product Name D-Con Ready Mixed Baitbits

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).	☑ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses .

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (I) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature	Date	Typed or Printed Name and Title
Liane Jenkins	10/9/06	Liane Jenkins, Regulatory Specialist

EPA Form 8570-34 (9-97) Electronic and Paper versions available. Submit only Paper version.

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 2-28-95

EPA

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☑ Other

OPP Identifier Number: 304863

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
3282-81	Julia Stokes	☑ None ☐ Restricted
4. Company/Product (Name)	PM#	
d-CON® Ready Mixed Baitbits		

5. Name and Address of Applicant *(Include ZIP Code)*

Reckitt Benckiser Inc.
399 Interpace Parkway
Parsippany, NJ 07054-0225

☐ *Check if this is a new address*

6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No._____

Product Name_____

Section II

☐ Amendment - Explain Below
☐ Resubmission in response to Agency Letter dated_____.
☐ Notification - Explain below.

☐ Final printed labels in response to Agency Letter dated _____.
☐ "Me Too" Application.
☑ Other - explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Additional Information for Reregistration

Section III

1. **Material This Product Will Be Packaged In:**

Child-Resistant Packaging	Unit Packaging		Water Soluble Packaging		2. Type of Container
☐ Yes* ☑ No	☑ Yes ☐ No		☐ Yes ☑ No		☐ Metal ☐ Plastic ☐ Glass ☑ Paper ☐ Other (Specify) _____
	If "yes," Unit Package wgt.	No. per container	If "Yes," Package wgt.	No. per container	

* ***Certification must be submitted.***

3. Location of Net Contents Information	4. Size(s) of Retail Container	5. Location of Label Directions
☐ Label ☑ Container		☑ On Label ☐ On Labeling accompanying product

6. Manner in Which Label is Affixed to Product ☐ Lithograph ☐ Paper glued ☐ Stenciled ☐ Other (_____)

Section IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this applicaiton.)*

Name	Title	Telephone No. (Include Area Code)
Liane Jenkins	Regulatory Specialist	(973) 404-2781

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false for misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title
Liane Jenkins	Regulatory Specialist
4. Typed Name	**5. Date**
Liane Jenkins	October 9, 2006

EPA Form 8570-1 (rev. 8-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460.
Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number	EPA Registration Number/File Symbol
Reckitt Benckiser Inc.,1655 Valley Road, Wayne,NJ 973-686-7390	3282-81
Active Ingredient(s) and/or representative test compound(s) Brodifacoum	**Date** April 23, 2002
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Household/Indoor	**Product Name** d-CON Ready Mixed Generation II

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

[XX] I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

[ ] I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

[XX] I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

[ ] I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses .

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (I) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature	Date	Typed or Printed Name and Title
Sean McNear	4/23/02	Sean McNear Sr. Regulatory Affairs Specialist

EPA Form 8570-34 (9-97) Electronic and Paper versions available. Submit only Paper version.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

APR 24 2007

Ms. Liane Jenkins
Registration Specialist
Reckitt Benckiser, Inc.
399 Interpace Parkway
Parsippany, NJ 07054-0225

RE: Minor Addition to the Label
EPA Registration Number: 3282-81
Date of Submission: January 16, 2007

Dear Ms. Jenkins:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 dated January 16, 2007, for the product d-CON® Ready Mixed Baitbits. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the actions requested fall within the scope of PRN 98-10. The label submitted with the application has been stamped "Notification" and will be placed in our records.

If you have any questions, please call me directly at 703-305-6249 or Joyce Edwards of my staff at 703-308-5479.

Sincerely,

Linda Arrington
Notifications & Minor Formulations Team Leader
Registration Division (7505P)
Office of Pesticide Programs

SIC

RECKITT BENCKISER

January 16, 2007

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
One Potomac Yard, Room S4900
2777 S. Crystal Drive
Arlington, VA 22202

Attention: John Hebert, PM-7

Ref.: **d-CON® Ready Mixed Baitbits**
- EPA Reg. No.: 3282-81
- OPP ID No.: 305607
- Minor additions to the label

Dear John,

Reckitt Benckiser is submitting a Notification to add minor changes to the Master Label for the above mentioned Registration. The additions we are adding are the following:

- (4) Bait Trays
- Adding a phone number for Spanish Instructions. The statement will be in Spanish. the English translations is as follows: Important: For directions for use and first aid instructions in Spanish, please call 1-866-648-1819."

There are no other changes made to the Master Label.

The enclosed documents support this registration action:

- EPA Application of Pesticide Registration, Form 8570-1, OPP ID No. 305607
- Certification Statement as per PR Notice 95-2

Thank you for your prompt assistance with this registration action. If you have any questions, please contact me at (973) 404-2781 or via e-mail at liane.jenkins@reckittbenckiser.com .

Sincerely,

Liane Jenkins

Liane Jenkins
Registration Specialist

RECKITT BENCKISER INC.
Morris Corporate Center IV, 399 Interpace Parkway, P.O. Box 225, Parsippany, NJ 07054-0225
Tel. (973)-404-2600 • Fax (973)-404-5700

Please read Instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 2-28-95

EPA

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☑ Other

OPP Identifier Number: 305607

Application for Pesticide - Section I

1. Company/Product Number: 3282-81
2. EPA Product Manager: John Hebert
3. Proposed Classification: ☑ None ☐ Restricted
4. Company/Product (Name): *d-CON® Ready Mixed Baitbits*
   PM#: PM-7
5. Name and Address of Applicant *(Include ZIP Code)*:
   Reckitt Benckiser Inc.
   399 Interpace Parkway
   Parsippany, NJ 07054-0225
   ☐ *Check if this is a new address*
6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to:
   EPA Reg. No._____
   Product Name_____

Section II

☐ Amendment - Explain Below
☐ Resubmission in response to Agency Letter dated_____.
☑ Notification - Explain below.
☐ Final printed labels in response to Agency Letter dated _____.
☐ "Me Too" Application.
☐ Other - explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Adding the following to the front panel label: (4) Bait Trays

Adding a phone number for Spanish Instructions. The statement will be in Spanish. the English translations is as follows "Important: For Directions for Use and First Aid instructions in Spanish please call 1-866-648-1819"

Section III

1. **Material This Product Will Be Packaged In:**

Child-Resistant Packaging	Unit Packaging		Water Soluble Packaging		2. Type of Container
☐ Yes* ☐ No	☐ Yes ☐ No		☐ Yes ☐ No		☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☐ Other (Specify) _____
* *Certification must be submitted.*	If "yes," Unit Package wgt.	No. per container	If "Yes," Package wgt.	No. per container	

3. Location of Net Contents Information: ☐ Label ☐ Container
4. Size(s) of Retail Container
5. Location of Label Directions: ☐ On Label ☐ On Labeling accompanying product
6. Manner in Which Label is Affixed to Product: ☐ Lithograph ☐ Paper glued ☐ Stenciled ☐ Other (_____)

Section IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this applicaiton.)*

Name	Title	Telephone No. (Include Area Code)
Liane Jenkins	Registration Specialist	(973) 404-2781

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false for misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title
Liane Jenkins	Registration Specialist
4. Typed Name	**5. Date**
Liane Jenkins	January 16, 2007

EPA Form 8570-1 (rev. 8-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

RECKITT BENCKISER

January 16, 2007

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
One Potomac Yard, Room S4900
2777 S. Crystal Drive
Arlington, VA 22202-4501
ATT: John Hebert PM 7

RE: d-CON Ready Mixed Baitbits
EPA Registration No.: 3282-81
Certification Statement per PR Notice 98-10

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Liane Jenkins
Regulatory Specialist

RECKITT BENCKISER INC.
Morris Corporate Center IV, 399 Interpace Parkway, P.O. Box 225, Parsippany, NJ 07054-0225
Tel. (973)-404-2600 • Fax (973)-404-5700

12 OZ AND 3 LB. OUTER BOX
FRONT LABEL

(GOOD HOUSEKEEPING SEAL)

d-CON®
READY MIXED BAITBITS

KILLS MICE AND RATS

CAN KILL IN ONE FEEDING
*Rats and mice may consume a lethal dose in one feeding with first dead rodents appearing 4 or 5 days after feeding begins.

Keep out of reach of children.
CAUTION: May be harmful or fatal if swallowed.
Read additional precautionary statements on back panel.

ACTIVE INGREDIENT:
Brodifacoum 3-[3-(4'-bromo-{1,1'-biphenyl}-4-yl)-1,2,3,4-tetrahydro-1-naphthalenyl]-4-hydroxy-2H-1-benzopyran-2-one.....0.005%
INERT INGREDIENTS: 99.995%
TOTAL 100.000%

4 READY TO USE BAIT FILLED TRAYS
4 BAIT TRAYS
NET CONTENTS 4/3.0 OZ. (85g) NET WT. 12 OZ. (340g)

16 READY TO USE BAIT FILLED TRAYS
NET WT. 3 LBS. (1360g)

Important: For Direction for use and first aid instruction in Spanish, please call 1-866-648-1819

12 OZ BOX AND 3 LB. OUTER BOX
BACK LABEL

d-CON READY MIXED GENERATION II

KILLS RATS AND MICE
Kills Warfarin-Resistant House Mice and Warfarin-Resistant Norway Rats

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

READ THIS LABEL: Read this entire label and follow all use directions and use precautions.

IMPORTANT: Do not expose children, pets, or other non target animals to rodenticides. To help prevent accidents:

1. Store product not in use in a location out of reach of children and pets.

2. Apply bait in locations out of reach of children, pets, domestic animals and non-target wildlife, or in tamper-resistant bait stations. These stations must be resistant to destruction by children under six years of age and must be used in a manner that prevents such children from reaching into bait compartments and obtaining bait. If bait can be shaken from stations when they are lifted, units must be secured or otherwise immobilized. Even stronger bait stations are needed in areas open to hoofed livestock, raccoons, bears, other potentially destructive animals, or in areas prone to vandalism.

3. Dispose of product container, and unused, spoiled, and unconsumed bait as specified on this label.

USE RESTRICTIONS: This product may be used to control House Mice, Norway Rats, and Roof Rats in and around homes, industrial, commercial, agricultural and public buildings. d-CON Ready Mixed Generation II may also be used in transport vehicles (ships, trains, aircraft) and in and around related ports or terminal buildings. Do not use in sewers. Do not place bait in areas where there is a possibility of contaminating food or surfaces that come in direct contact with food. Do not broadcast bait.

SELECTION OF TREATMENT AREAS: Determine areas where rats or mice will most likely find and consume the bait. Generally, these are along walls, by gnawed openings, in or beside burrows, in corners and concealed places, between floors and walls, or in locations where rodents or signs of rodents have been seen. Remove as much alternative food as possible. Use tamper-resistant bait stations wherever necessary (see **"IMPORTANT:"**).

APPLICATION DIRECTIONS:
(FOR 12 OZ. BOX ONLY: The amount of bait contained in the trays in this box is unlikely to be sufficient to kill more than 3 to 12 rats. More than one box may be needed to control larger infestations.

To Control Norway and Roof Rats: Place 1 - 4 bait trays per placement. Space placements at intervals of 15 - 30 feet in infested areas. If trays are not fed for 5 consecutive days, relocate them to other places where rodent activity exists and where placements consistent with the requirements of this label can be made. Maintain an uninterrupted supply of fresh bait for at least 10 days.

To Control House Mice: Open tray and apply 1/4 - 1/2 oz. (1 - 2 level tablespoons) of bait at 8 to 12 foot intervals in infested areas. Larger placements (up to 2 ounces) may be needed at points of extremely high mouse activity. Maintain a supply of fresh bait for at least 15 days.

Check bait locations every 2 days for signs of feeding. Replenish bait if more than 1/2 of the original amount has been removed by rodents. Replace contaminated or spoiled bait immediately if rodent activity is still evident. Collect and dispose of all dead animals and leftover bait properly.
To prevent reinfestation, limit sources of rodent food, water and harborage as much as possible. If reinfestation does occur, repeat treatment. Where a continuous source of infestation is present, establish permanent bait stations and replenish as needed.

PRECAUTIONARY STATEMENTS:
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
CAUTION: May be harmful or fatal if swallowed. Keep away from humans, domestic animals, and pets. Wash hands after handling bait. IF BAIT IS EATEN BY HUMAS, CALL A PHYSICIAN AT ONCE. For 24 hour emergency assistance, call your local Poison Control Center. IF BAIT IS EATEN BY ANIMALS OR PETS: Call your local veterinarian.
NOTE TO PHYSICIAN AND VETERINARIAN: This product may reduce the clotting ability of the blood and cause hemorrhaging. The anticoagulant action of this product may produce prolonged prothrombin times for 20 to 30 days after exposure. If poisoning occurs, intramuscular and oral administration of Vitamin K_1 are indicated, as in poisoning from overdose of dicumarol (bishydroxy coumarin). **FOR HUMAN CASES**: Vitamin K_1 is antidotal at doses of 10 to 20 mg (not mg/kg). Repeated treatments may need to be given for up to 30 days (based on monitoring of prothrombin times). In severe cases, blood transfusions may be necessary. **FOR ANIMAL CASES**: Contains Brodifacoum, an anticoagulant with a half-life in the dog of 1 – 4 days. For dogs that have ingested or that are suspected of having ingested Brodifacoum, and/or have obvious poisoning symptoms, such as bleeding or have lowered prothrombin times, give Vitamin K_1 as follows: Vitamin K_1 is antidotal at 5 mg/kg intramuscularly. Oral Vitamin K_1 should be given for up to 30 days at 5 mg/kg (based on monitoring of prothrombin times). In severe cases blood transfusions may be necessary.

ENVIRONMENTAL HAZARDS: This product is toxic to fish, birds and wildlife. This product can pose a secondary hazard to birds of prey and mammals. Do not apply directly to water.

STORAGE AND DISPOSAL

STORAGE: Store only in original container, in a dry place inaccessible to children and pets.

DISPOSAL: Do not reuse empty container. Securely wrap contained and any unused bait in newspaper and discard in trash.

Important: For Direction for use and first aid instruction in Spanish, please call 1-866-648-1819

12 OZ. BOX RIGHT SIDE PANEL

d-CON®
PELLETS GENERATION II

KILLS MICE AND RATS

Kills Warfarin-Resistant
House Mice and
Warfarin-Resistant
Norway Rats

NOTICE TO BUYER AND USER: Seller warrants that this product conforms to the chemical description on the label and is reasonably fit for the purpose stated on the label when used in accordance with directions under normal conditions of use. This warranty does not extend to the use of this product contrary to label instructions, or under abnormal use conditions, or under conditions not reasonable foreseeable to Seller, and Buyer and User assumes the risk of any such use.

SELLER DISCLAIMS ALL OTHER WARRANTIES EXPRESSED OR IMPLIED INCLUDING ANY WARRANTY OR FITNESS OR MERCHANTABILITY. SELLER SHALL NOT BE LIABLE FOR CONSEQUENTIAL, SPECIAL OR INDIRECT DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT AND SELLER'S SOLE LIABILITY AND BUYER'S AND USER'S EXCLUSIVE REMEDY SHALL BE LIMITED TO THE REFUND OF THE PURCHASE PRICE.

EPA Reg. No. 3282-81
EPA Est. No. 475-MS-1; 2393-WI-1

SATISFACTION
GUARANTEED OR
YOUR MONEY BACK

Important: For Direction for use and first aid instruction in Spanish, please call 1-866-648-1819

12 OZ. BOX LEFT SIDE PANEL

d-CON®
PELLETS GENERATION II

KILLS RATS AND MICE

CAN KILL INONE FEEDING*

*Rats and mice may consume a lethal dose in one feeding with first dead rodents appearing 4 or 5 days after feeding begins.

MADE IN THE USA

d-CON BAITS:
KILLING RATS AND MICE IN AMERICA
FOR 50 YEARS

SATISFACTION
GUARENTEED OR
YOUR MONEY BACK

Distributed by:
Reckitt Benckiser Inc
Parsippany, NJ 07054

Important: For Direction for use and first aid instruction in Spanish, please call 1-866-648-1819

3 OZ. BAIT TRAY
FRONT PANEL

d-CON®
PELLETS GENERATION II

KILLS RATS AND MICE

READY-TO-USE BAIT TRAY

Kills Warfarin-Resistant House Mice and Warfarin-Resistant Norway Rats

CAN KILL INONE FEEDING*
*Rats and mice may consume a lethal dose in one feeding with first dead rodents appearing 4 or 5 days after feeding begins.

Keep out of reach of children.
CAUTION: May be harmful or fatal if swallowed.
Read additional precautionary statements on back panel.

ACTIVE INGREDIENT: Brodifacoum 3-[3-(4'-bromo-{1,1'-biphenyl}-4-yl)-1,2,3,4-tetrahydro-1-naphthalenyl]-4-hydroxy-2H-1-benzopyran-2-one.....0.005%
INERT INGREDIENTS: 99.995%
TOTAL 100.000%

NET WT. 3 OZ. BAIT TRAY (85g)

3 OZ. BAIT TRAY
BACK PANEL

Kills Warfarin-Resistant Norway Rats and Warfarin-Resistant House Mice.

DIRECTIONS FOR USE

~~It is a violation of Federal law to use this product in a manner inconsistent with its labeling.~~
Read the entire label on the outer package before using this product. It is illegal to sell these bait trays individually.

PRECAUTIONARY STATEMENTS:
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
KEEP OUT OF REACH OF CHILDREN.
Place bait in areas not accessible to children, pets, domestic animals or wildlife or in tamper-resistance bait boxes.
CAUTION: May be harmful or fatal if swallowed. Keep away from humans, domestic animals, and pets. Wash hands after handling bait. IF BAIT IS EATEN BY HUMANS, CALL A PHYSICIAN AT ONCE. For 24 hour emergency assistance, call your local Poison Control Center. IF BAIT IS EATEN BY ANIMALS ORPETS: Call your local veterinarian.
NOTE TO PHYSICIAN AND VETERINARIAN: This product may reduce the clotting ability of the blood and cause hemorrhaging. The anticoagulant action of this product may produce prolonged prothrombin times for 20 to 30 days after exposure. If poisoning occurs, intramuscular and oral administration of Vitamin K_1 are indicated, as in poisoning from overdose of dicumarol (bishydroxy coumarin). **FOR HUMAN CASES**: Vitamin K_1 is antidotal at doses of 10 to 20 mg (not mg/kg). Repeated treatments may need to be given for up to 30 days (based on monitoring of prothrombin times). In severe cases, blood transfusions may be necessary. **FOR ANIMAL CASES**: Contains Brodifacoum, an anticoagulant with a half-life in the dog of 1 – 4 days. For dogs that have ingested or that are suspected of having ingested Brodifacoum, and/or have obvious poisoning symptoms, such as bleeding or have lowered prothrombin times, give Vitamin K_1 as follows: Vitamin K_1 is antidotal at 5 mg/kg intramuscularly. Oral Vitamin K_1 should be given for up to 30 days at 5 mg/kg (based on monitoring of prothrombin times). In severe cases blood transfusions may be necessary.
ENVIRONMENTAL HAZARDS: This product is toxic to fish, birds and wildlife. This product can pose a secondary hazard to birds of prey and mammals. Do not apply directly to water.

ACTIVE INGREDIENT: Brodifacoum 3-[3-(4'-bromo-{1,1'-biphenyl}-4-yl)-1,2,3,4-tetrahydro-1-naphthalenyl]-4-hydroxy-2H-1-benzopyran-2-one.....0.005%
INERT INGREDIENTS: 99.995%
TOTAL 100.000%

Distributed by:
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